UNITED STATES OF AMERICA
FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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TECHNICAL ELECTRONIC PRODUCT RADIATION SAFETY STANDARDS COMMITTEE

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29th Meeting

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WEDNESDAY,
MAY 22, 2002

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This is a corrected version of the transcript. These edits were to correct spelling errors or clarify terminology. In no cases were the contents of recorded statements altered.

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The Committee met at 8:30 a.m. in Salon of the Hilton Washington, D.C. North, 620 Perry Parkway, Gaithersburg, Maryland, Dr. Lawrence Rothenberg, Chairman, presiding.

PRESENT:

LAWRENCE ROTHENBERG, Ph.D., Chairman
JANE BENSON, M.D., Member
MICHAEL CASWELL, Ph.D., Member
ALICE FAHY-ELWOOD, M.S., Member
DAVID LAMBETH, Ph.D., Member
JILL LIPOTI, Ph.D., Member
MICHELE LOSCOCCO, M.S., Member
W. GREGORY LOTZ, Ph.D., Member
KIYOHIKO MABUCHI, M.D., Member
MAUREEN MURDOCH NELSON, M.D., Ph.D., Member
ROBERT PLEASURE, J.D., Member
JOHN SANDRIK, Ph.D., Member

ORHAN SULEIMAN, M.S., Ph.D., Executive Secretary

C-O-N-T-E-N-T-S

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P-R-O-C-E-E-D-I-N-G-S

(8:38 a.m.)

DR. SULEIMAN: On the record. Before we get started, I'll also advise all the Committee Members that when you speak could you bring the microphone closer so our electronic system can pick it up. I'd like to welcome everybody this morning. In the interest of time and efficient management, let's get started.

I'm Orhan Suleiman, the Executive Secretary for the Technical Electronic Product Radiation Safety Standards Committee. I need to read something to get us started officially. Let me do that. Then I'll pass off to Dr. Rothenberg who is the Chair of the Committee.

"In accordance with the Radiation Control for Health and Safety Act of 1968, Public Law 90-602, the Secretary of Health and Human Services has established the Technical Electronic Product Radiation Safety Standards Committee, TEPRSSC, for consultation on matters relating to technical, electronic, product, radiation, safety. As specified by the law, the Committee consists of 15 members including the Chairman who are appointed by the Commissioner of Food and Drugs for

overlapping terms of four years or less. Five members are selected from Governmental Agencies including State and Federal Governments, five members from the affected industries, and five members from the general public of which at least one shall be a representative for organized labor.

Members must be technically qualified by training and experience in one of more fields of science or engineering applicable to electronic, product, radiation, and safety standards. The primary function of TEPRSSC is to provide advice and consultation to the Commissioner of Food and Drugs on the technical feasibility and reasonableness of performance standards for electronic products, to control the emission of electronic product radiation from such products, and to review amendments to such standards before being prescribed by the Commissioner.

The Committee is not requested to review individual applications or particular products of specific firms. Public Law 90-602 in its legislative history clearly indicated that the TEPRSSC members are expected to represent a wide range of interests with at least one-third of the Committee nominated by the regulated industry

itself and appointed on the basis of their being able to represent industry wide concerns.

Section 534 of the Federal Food, Drug and Cosmetic Act specifies that TEPRSSC members are not to be considered officers or employees of the United States for any purpose including conflict of interest determinations. However, to be consistent with FDA's general policies regarding advisory committees, the Agency believes a public disposer memorandum should be made a part of the public record which identifies each member and provides their employment affiliation. Approved on August 30, 1999, June 9, 2000, April 24, 2002, by delegated authority of the Commission of Food and Drugs."

The members of the Technical Electric Product Radiation Safety Standards Committee are the general public members; Larry Rothenberg from Memorial Sloan-Kettering, William Rice from American Radiology, Francis Gasparro from Cheshire High School, Robert Pleasure from the Center for Working Capital, actually as of July he's now with the AFL-CIO Center for Working Capital, and Jane Benson from the Johns Hopkins University School of Medicine.

Government representatives are Greg Lotz from the National Institute for Occupational Safety and Health, Michele Loscocco from United States Navy Joint Readiness Clinical Advisory Board, Kiyohiko Mabuchi from the National Cancer Institute, Jill Lipoti from the Department of Environmental Protection and Energy from New Jersey, and Maureen Murdoch Nelson from the Veterans Administration Medical Center.

Representatives of industry when they were originally appointed are Alice Fahy-Elwood represented Lucent Technologies, John Sandrik from General Electric Medical Systems, David Lambeth from Lambeth Systems, Michael Caswell from C.B. Fleet Company, and Quirino Balzano from Motorola Florida Laboratories. At this point I'd like to pass off to Dr. Rothenberg.

CHAIRMAN ROTHENBERG: I'd like to welcome everyone on behalf of the Committee and thank the Committee Members for taking time out from their busy schedules to participate. We have a rather extended schedule today. In order to cover the materials which will be presented, we want to keep everything moving along smoothly.

I'd just like to remind you that we

have several scheduled speakers. The Committee Members of course are free to participate in all of the discussions. We will certainly hope that they will participate extensively. For those of you on the floor, we must remind you that you have to be recognized by the Chair in order to speak. We'll try to accommodate input as time permits.

I think with that you've heard the names of the members but maybe just to be sure everyone is clear who the Committee Members are if we could just start with Ms. Fahy-Elwood on my right and just go around briefly. Please introduce yourselves.

MS. FAHY-ELWOOD: I'm Alice Fahy-Elwood. I'm a health physics consultant to industry.

DR. NELSON: I'm Maureen Murdoch Nelson. I'm a general internist at the Minneapolis VA Medical Center.

DR. LIPOTI: I'm Jill Lipoti. I work for the New Jersey Department of Environmental Protection.

DR. BENSON: I'm Jane Benson. I'm a pediatric radiologist at Johns Hopkins Hospital.

DR. MABUCHI: I'm Kiyo Mabuchi. I'm an

epidemiologist from the National Cancer Institute.

DR. LAMBETH: I'm David Lambeth. I'm at Carnegie-Mellon University.

DR. CASWELL: I'm Mike Caswell. I'm Director of Scientific Affairs at C.B. Fleet Company, Incorporated.

DR. SULEIMAN: I'm Orhan Suleiman with FDA.

CHAIRMAN ROTHENBERG: Larry Rothenberg with Memorial Sloan-Kettering Cancer Center.

DR. SANDRIK: I'm John Sandrik an imaging physicist in GE Medical Systems.

MS. LOSCOCCO: Michele Loscocco, U.S. Navy. I executed a transfer this week from the Joint Readiness Clinical Advisory Board to the National Naval Medical Center.

DR. LOTZ: Greg Lotz. I'm with the radiation research programs at NIOSH in Cincinnati.

MR. PLEASURE: Robert Pleasure, AFL-CIO Center for Working Capital.

CHAIRMAN ROTHENBERG: Okay. We're missing two members of the Committee. We're hoping they will show up. Dr. William Rice, a practicing community radiologist and Francis Gasparro with research experience in photobiology. I think at

this point we'd like to proceed with the program so we'd like to welcome Ms. Lillian Gill who will give us an update of informal issues with the CDRH.

MS. GILL: Good morning, Committee. Good morning, audience. I'd like to add my welcome to Dr. Suleiman and Dr. Rothenberg. I welcome all of you to this meeting of the TEPRSSC Advisory Committee. I really want to extend a special welcome to those five new committee members that are joining us for the first time.

We're pleased that you have made time in your crowded schedules to consult with and to advise us on key issues that are on the agenda such as the computed tomography, sunlamp products and personnel screening systems. Before our experts begin their presentations, I want to provide you with an update on some of the issues that have been discussed with this Committee before particularly four.

First I'd like to bring an update on the wireless cell phone CRADA. CDRH continues to receive a number of inquiries about the safety of wireless phones. In order to ensure that the needed research is conducted to address the public concern, the CDRH has signed a Cooperative Research

and Development Agreement with the Cellular Telecommunications and Internet Association or CTIA. Under this CRADA agreement, CDRH provides research recommendations and research oversight while CTIA funds the research into the health effect of radio frequency emissions from wireless phones.

In fiscal year 2000, the CDRH made recommendations on the follow up research needed to address reported structural changes in the genetic material of lymphocytes after exposure to signals from a wireless phone. The CDRH is currently providing scientific oversight to those proposals that were funded in this area.

In fiscal year 2001, the CDRH convened two scientific meetings to define the epidemiological research needs related to use of wireless phones. Based on the input received at these meetings, CDRH submitted its recommendations on the epidemiology research needs to CTIA.

Turning to the status of the laser amendments. At your last meeting, I provided a progress report on the proposed amendments to the laser standard. We are continuing to amend this standard because of some more recent scientific

knowledge received on laser bio-effects and because we are harmonizing our requirements with those of the International Electrotechnical Commission.

I also indicated at that meeting that the technical writing of the standard and the preamble had been completed. Since then some additional requirements have been made to both documents. Because the regulated industry was so strongly in favor of our plan to amend, we provided temporary relief to the industry last year while those documents continued to move through the process.

A guidance document entitled "Laser Nos. 50" was issued stating that we would not object to industry's compliance with those requirements of the IEC standard of which we announced our intention to incorporate into the standard changes. Those aspects involved the new designation of hazard classification, radiometric measurements for classification, reduced controls and indicators for power lasers, and some labelling aspects.

Although the progress of this has moved a bit slower than we planned at the present time we are working with the FDA economics staff to develop

an economic analysis of the impact of these amendments on the regulated industry. This analysis is a necessary step in the process of paving clearance by our Office of Management and Budget for publication of this amendment. We found this analysis to be both lengthy and difficult because of its diversity of products and the companies within the laser product industries.

Regarding the fluoroscopy amendments, FDA's efforts to publish the proposed amendments to the performance standard for diagnostic X-ray systems also continues. These amendments primarily addressing fluoroscopic X-ray systems have been discussed in detail at these meetings. Since the May 2001 meeting, the review at FDA was completed and the draft Federal Register notice was forwarded to the Department. We did receive feedback from the Department and a number of suggestions that we place some additional emphasis in the Notice of Proposed Rulemaking regarding the monetary costs and benefits of these proposed amendments.

The cost of the amendments had previously been described in our draft analysis. It was made available on our web site as we solicited some comments. The benefit analysis

which was summarized in more detail in that Notice of Proposed Rulemaking was presented at our 2001 Science Symposium last February and has also been posted on our web site for review by interested parties.

The revise of the NPR has been reviewed again by FDA and has been forwarded once again to the Department for review. Because they agreed and concurred with the draft NPR that they initially reviewed given we made changes to the impact assessment regarding cost and benefits, we are hopeful that we get publication in the near future and I'll be able to give you a positive report on that at the next meeting.

When published, this NPR will specify a 120 comment period during which time the industry, the medical community and the interested public can provide comment on the proposed amendments. The Agency then has the responsibility for reviewing those comments and hopefully proceeding to publication of the final rule.

Lastly I want to mention some of the activities that have been going on for counter-terrorism and the response to radiological threats. Like most Government Agencies, we've been very

much involved in a number of counter-terrorism activities. For the past 30 years, the major concentration of radiological expertise in FDA was in the Center for Devices and Radiological Health and its predecessor, the Bureau of Radiological Health.

During that period, they served as the Agency's focal point for reacting to domestic radiological emergencies, routinely participating in multi-Agency and FDA headquarter planning activities and exercises, and responding to some real events such as Three Mile Island. Last fall, it became very conceivable that terrorists would attempt to employ nuclear or radiological weapons in the United States.

Consequently when the FDA Office of Regulatory Affairs who has the responsibility for emergency planning for the Agency began the modification of the FDA Radiological Emergency Response Plan, the Center and other sister centers within FDA began the modification of our individual response plans to incorporate counter-terrorist preparation. All plans across FDA will ultimately be harmonized with the Response Plan of the Department of Health and Human Services.

Among the other things, the CDRH plan recognized the need to manage two categories of radiological hazards. The first category is the use of abuse of electronic radiation-emitting devices. These are devices that may be used by terrorists such as the aiming of lasers at aircraft to blind airline pilots making night landings or those used inappropriately by security personnel resulting in a potential over exposure to the public. The second category is the use of radioactive material as nuclear weapons, "dirty bombs" and -- devices or high activity sources clandestinely positioned to expose the public.

Separate emergency response teams under our plan were created to deal with these two categories. CDRH working with the radiological response cadre that was formed some years ago to respond to domestic accidents established a larger cadre of personnel with skills appropriate to those functions needed by the Emergency Operations Center. About two months ago, this center offered a new cadre, a basic course in radiation physics and information on the roles and responsibilities of Federal Agencies that are participating in the Federal Emergency Response Structure.

Personnel in other centers and members of our field staff who are located around the U.S. were invited to attend and participated as trainers in the course. Our training will continue on specific duties in the Emergency Operations Centers as we go forward. The center does not plan to send response teams to assist at an incident site, not initially. Instead the Agency will utilize the regional and district field personnel who have continuously participated in our exercises and are there to respond to the scene of real events. Exceptions to this will be center employees who are officers of the Public Health Service Commissioned Corps.

The CDRH will have two functions; both a support and a communication function. The first is support of the regional and district teams. The second includes guidance to the public, technical consultations to professionals and to the regulated industry. I've given you a very brief summary of four activities that are ongoing at CDRH. I think we have experts and those who have been working specifically on those amended standards in the audience if you should have additional questions on those. Thank you.

CHAIRMAN ROTHENBERG: Okay. Thank you very much. Does anyone on the Committee have any questions for Ms. Gill?

DR. NELSON: As I recall at the last meeting specifically talking about cell phones, we had talked about encouraging these studies to look at a wide variety of outcomes, not necessarily cancer as the only outcome. Can you tell me what kinds of studies are ongoing in terms of what outcomes they're looking at?

MS. GILL: I can't specifically tell you that. Unfortunately we did lose our coordinator for that. I'm not sure Howard Cyr is here. Howard isn't available to give you some specifics on that, but he should be in the afternoon able to provide you with some of those.

CHAIRMAN ROTHENBERG: Okay. Anyone else?

DR. LIPOTI: Is there any time frame for when the fluoroscopy amendments might be published? How long does it take for the Department to review things? Do they then have to leave the Department and go before the Office of Management and Budget and so forth?

MS. GILL: That is the process. I

really can't give you a specific on when we expect it to be through. Certainly events that have occurred since we submitted it have put these kinds of things on the backburner. Because they have reviewed, I'm certainly planning and hoping that they will move this a little more quickly. Sometimes that happens if they've seen it before and they're aware of the issues involved. I'd like to be able to say we can get it out of there in the next four to six months but I'm not sure. I don't know if you have any additional information.

CHAIRMAN ROTHENBERG: Is Tom Shope here? Do you have anything to add?

MR. SHOPE: Away from microphone.

CHAIRMAN ROTHENBERG: Thank you. Okay. If there are no further questions, thank you very much for your report. Our next presentation is going to be by Dr. Stanley Stern on computed tomography and proposed amendments.

DR. STERN: It will be just a few moments while we get everything coordinated with the computer and the projector.

DR. LIPOTI: Larry, while they're figuring out the computer, could I ask one more question about the counter-terrorism issue?

CHAIRMAN ROTHENBERG: Sure.

DR. LIPOTI: There were two functions that headquarters would have. One is the support of the regional and district personnel and the other one was communication. Communication with the public was what I gathered. What kinds of tools are you developing for communication with the public? Is it on radiological hazard or is it on food?

MS. GILL: We're working with our sister centers. Our Center for Drugs has responsibility for the potassium iodide distribution. Our Center for Foods certainly has responsibility for any contaminant or any radiological impact on food issues. So it would be communication about red health issues specifically from CDRH, from both centers.

There is a larger plan that the Agency has developed. It speaks to counter-terrorist issues across all devices so there's a specific element for red health issues. All three centers are coordinating our plan for that.

We've developed and will be developing probably a command center that mans the phone. We will be putting out on the web site names, contact

persons, things like that. As you might understand, we're a little bit skeptical of putting out the full plan on the web site. I think enough information for the public to make some contact and any other way that they might get information. We're providing information and training to the field, to anything that the states may need, and we can be available to go if asked.

DR. LIPOTI: Thanks.

CHAIRMAN ROTHENBERG: Thank you again. I think our projector is now functioning, so Dr. Stern.

DR. STERN: Thank you very much. This presentation grows out of the collaborative efforts of an FDA group of science, regulation and economics staff. We're working to facilitate radiation dose reduction through consideration of amendments to the existing CT performance standard. Our motivation is the proposition that the current Federal regulations covering CT, in place since the mid-1980s, have not kept pace with technological developments and with the need to assure the lowest dose for the best image quality practically achievable.

The work group's current thinking and

my own personal ideas and analysis presented here do not necessarily reflect any official position of the FDA or its components. Many items in the slides are annotated with superscripted numbers that cite references and notes listed at the end of the presentation. Reference to any products, manufacturers, models of CT systems or external web sites does not imply FDA endorsement.

The theme of the introductory part of this presentation is the interplay of technology and clinical practice in CT, how the rapid technological and clinical advances of the past few years have increased CT use and have led to public-health concerns. This theme is a basis for background discussion and for updates on the activities CDRH has undertaken to address these concerns since I spoke about them last year.

Computed tomography is a vitally important, beneficial modality whose radiation doses are relatively higher than those of most other X-ray exams. The scope of CT applications is broad, and CT is used in many different ways, from diagnosis, to cancer staging, to treatment planning, and more recently for real-time visualization during interventional operations.

This slide summarizes those physical, geometrical, and mechanical aspects of currently predominant CT technology that bear on individual radiation-dose delivery. Electron-beam CT is not covered here because e-beam CT scanners make up perhaps only 1 to 2 percent of approximately 10,000 CT units in the U.S.

The essential feature of X-ray CT irradiation is a thin, fan-shaped X-ray beam that rotates around a patient. In most systems, X-ray detectors are located beyond the patient diametrically opposite the X-ray source, and the beam and detectors rotate together while the detectors register X-rays transmitted through the patient. In the figure, the X-ray beam is indicated by the red shading, and the detectors are indicated by green.

A single 360 degree rotation typically takes from one-half to one second, a relatively brief period compared to rotation times of ten years ago. An important point is that while some of the most recent models of scanners now offer different options that enable a system to automatically adjust radiation output higher or lower to account for a patient's circumference, in

most systems the radiological techniques, such as the peak X-ray tube voltage (kVp), the X-ray tube current (mA), the rotation time, need to be set manually by the CT technologist. In an ideal workplace, these settings are based on a technique chart which a facility would develop covering different examination protocols and various sizes of patients.

What's referred to as a single “slice” corresponds to a thickness usually between 1 and 10 millimeters along the length of a patient, and it yields one cross-sectional image per single rotation. Single-slice scanners are distinguished from CT systems that are capable of doing multi-slice scanning.

Spiral multi-slice scanners were introduced only four years ago, and when they operate in multi-slice mode, they produce two to four cross-sectional images simultaneously per rotation. These images correspond to adjacent slices along the length of the patient. Newer spiral scanner models can provide eight and even 16 slices simultaneously, and in the next few years they will probably replace most of the axial-only models.

In axial CT, the table moves increment-by-increment following each single rotation. Spiral scanning, also called “helical” scanning, refers to table movement at a constant rate during continuous rotations. It's called spiral or helical because the combination of smooth table movement and X-ray source rotation leads to the X-ray field tracing out a helical path around the patient.

The direction along the length of the patient is referred to as the “z-axis”, the axis about which the beam and detectors rotate. Typically in a single phase of a CT examination the table movement spans a range covering on the order of 10 to 50 slices along the length of a patient.

The features of fast, multi-slice spiral CT have enabled scanning of large volumes of patient anatomy, three-dimensional rendering of images, angiography, single-breath-hold imaging and visualization of small lung nodules. The bottom line is that these advances in CT technology have been rapidly adopted into clinical practice and have led to an explosive growth in the number of applications, to a capability of examining patients quickly, and to a high rate of use.

The items on the left-hand side of this slide underscore some public-health concerns ensuing from the growth in use of CT. The right-hand side lists the preliminary responses of CDRH in addressing these concerns. First, we are faced with the problem of determining the scope of radiological exposure from CT. How many CT examinations are going on annually and just how large are the doses from what particular exams?

CDRH provided the principal technical direction for a survey conducted through the Nationwide Evaluation of X-ray Trends (N.E.X.T.) program administered by the Conference of Radiation Control Program Directors. Between April 2000 and July 2001 state inspectors surveyed examination doses and workloads in 263 CT facilities randomly selected in 39 states to provide the first national understanding of the magnitude of collective dose from CT since the first CT survey in 1990 in the United States.

A related project is the ongoing development of a handbook of patient doses associated with approximately 50 of the most common CT examinations. Such a handbook would foster risk communication between medical staff and patients,

and it would enable medical physicists and radiologists to evaluate patient tissue doses and effective dose for their facility's CT systems and adjust their protocols as needed to reduce doses.

With respect to the second item, in February 2001 the American Journal of Roentgenology published a series of papers describing the potential risk associated with inappropriate equipment settings and scanning techniques in CT examinations of children. A great deal of publicity resulted from these studies, and our concerns were voiced at the last meeting of TEPRSSC. Following the advice of TEPRSSC, last November CDRH issued a Public Health Notification to radiologists, radiation health professionals, risk managers, and hospital administrators alerting facilities to the problem and providing practical advice on how to reduce risk associated with CT dose in pediatric and small adult patients.

Since that time there has been burgeoning popularization of a group of applications commonly referred to as CT “screening” of self-referred individuals who are asymptomatic of any particular disease. Among these applications are included “whole-body”

examinations, examinations of the lungs for cancer, and “calcium-scoring” of the heart as a purported indicator of potential heart disease. Right now CT screening makes up only a tiny fraction of the number of CT procedures performed annually in the U.S.

Our main concerns are the risks associated with false positive results and with radiation dose. False positive results could needlessly lead to follow up tests or procedures that might be invasive - associated with surgical risks of anesthesia, bleeding, infection, scarring - or entail additional radiological exams. Radiation doses in diagnostic CT are among the highest of those of all X-ray modalities, and screening CT doses are significantly large even when “low-dose” protocols might be applied.

There are no scientific studies demonstrating that whole-body CT screening of asymptomatic people is efficacious. Were it a useful screening test, it would be able to detect particular diseases early enough to be managed, treated, or cured and advantageously spare a person at least some of the detriment associated with serious illness or premature death. At this time

such presumed benefit of whole-body CT screening is in fact uncertain, and the benefit may not be great enough to offset the potential harms such screening could cause.

FDA has recently posted a web page about CT screening. The page provides information about our concerns, contains brief explanations of computed tomography, radiation risks, radiation quantities and units, the regulatory status of CT, and includes links to related resources. It is hoped that an objective presentation from a Government institution whose fundamental mission is to protect public health will clarify the natures of the risks and presumed benefits in a way that persuades people to carefully consider these aspects of CT screening before deciding whether or not to have such exams.

With respect to the last item in the slide, we are aware of the small but growing use of what's called "CT fluoroscopy" or "dynamic CT" to visually guide interventional procedures involving biopsy, drainage, and device placement. "CT fluoroscopy" refers to the capability of a CT system to update images in nearly real time as the X-ray field and detectors rotate multiple times

around a patient at a fixed z position, that is, without table movement.

Recent reports cite mean values of entrance skin dose of approximately 100 to 400 mGy, below the threshold for skin injury. Several years ago a small CDRH group drafted guidance for reviewers and manufacturers of CT systems capable of CT fluoroscopy, but the move to formal adoption of final guidance has been on hold in view of the relatively small probability for skin injury in the most common procedures and also since preliminary findings of the 2000 CT survey indicated that only 5 percent of the most frequently used CT units in facilities have the capability of doing CT fluoroscopy.

The baseline of radiation protection with respect to CT equipment is prescribed by the Federal Government through performance standards established under the Radiation Control for Health and Safety Act. The regulations in place now date back approximately 20 years. These rules apply to manufacturers of CT equipment, not to the facilities that use the equipment. The basic mandate is documentary: Manufacturers must provide users with specified documentation of dose values

for CT systems under typical operating conditions. Because this mandate predates special or new modalities such as electron-beam, multi-slice, spiral, fluoroscopic, or cone-beam CT, the doses manufacturers report don't necessarily pertain to those modes of operation. There is no regulatory ceiling on patient dose, and there are few major equipment requirements particular to CT per se.

The current FDA standard for CT dose documentation is represented by the computed tomography dose index, abbreviated “CTDI”. CTDI incorporates a number of the physical aspects associated with the geometry and irradiation conditions of computed tomography. These aspects include a rotating fan-shaped beam, collimation of the primary radiation to a thin slice along the z axis, the axis of rotation, broad scattering of the primary radiation by the material it passes through, and scattered-radiation contributions to the dose that are cumulative with multiple rotations.

CTDI is an index of dose, a descriptor or indicator of the magnitude of dose associated with the radiation output of a specific CT model. It is not a measure of patient dose on a person-by-

person basis. CTDI is a representation of dose which is standardized for specific reference materials and reference-procedure conditions. It's measured in a cylindrical phantom made of nearly solid acrylic, with diameter either 16 centimeters to correspond to the adult head or 32 centimeters to the adult body.

The figure in the center of the slide depicts a cylindrical phantom, and to the left is a face view of the phantom within the fan beam indicated by the red shading. The X-ray source is at the apex on the bottom, and the X-ray detectors are indicated by the green shading at the top. In a single scan, the fan beam and detectors rotate as an ensemble once around the central axis represented in the figure on the left by the origin of the x-y coordinate system. This central axis of rotation is the z axis.

Even though the CT radiation intended for image formation is collimated within a relatively thin section along the z axis, much radiation actually scatters throughout the phantom or patient. In the center figure, the red shading corresponds to the primary radiation passing through the phantom to the detectors, and the dark

blue-green shading represents the scattered radiation. So the dose is actually distributed, not localized exclusively to the narrow region collimated.

The figure on the right is called the dose "profile," and it represents the distribution of dose along the z axis for a single slice. The abscissa corresponds to position along the z axis, where 0 millimeters is at the center, and the ordinate is the dose in units of mGy. In your notes perhaps a previous version of the slide has units of rad. It's an older version of dose units. For single-slice scanners, the z-axis collimation of the system defines the slice thickness, designated by the letter “T” here, and in this example T is 13 millimeters. One sees that although most of the primary radiation is contained within the 13 millimeter wide central zone of the phantom, the scattered radiation extends far beyond the central zone, to more than 100 millimeters on either side. Furthermore, when there are multiple scans extending over a range along the patient length, as there are in most CT exams, at any one location along the z axis the scattered radiation from these other scans cumulatively adds to the

dose.

FDA therefore defined the dose index CTDI to be proportional to an integral which include the dose contributions from scattered as well as primary radiation over a range of the dose profile extending from negative seven to positive seven times the slice thickness T. In the example depicted, for a slice thickness of 13 millimeters, the range of integration is from -91 millimeters to +91 millimeters, covering practically all of the dose contributions, and the CTDI here is 8.2 mGy, or 0.82 rad. An advantage of defining a dose index this way is that mathematically CTDI is identical to the average dose in the central plane of 14 contiguous axial scans. In other words, the integral appropriately accounts for the dose contributions of adjacent, nearby slices, each with its own single-slice profile. So one can think of CTDI as the dose associated with a reference procedure: It is the average central-plane dose for a 14 slice exam, a reasonable representation of how exams were done 20 years ago.

From today's perspective, there are several problems with the regulatory definition of CTDI. CTDI is simply not defined for spiral CT

scanning, which is how most body exams are done currently. For spiral scanning the irradiation geometry and dose profile are different than these figures depict. Also, spiral scanning or no, the regulatory definition of CTDI does not account for CT procedures where the slices are not adjacent, that is, where slices may be separated by gaps or where they may overlap.

Over the years medical physicists have introduced a number of non-regulatory variants of CTDI that have been adopted into practice and to some extent by manufacturers. For example, it is much easier to measure CTDI with a fixed-length, 100 millimeter long ionization chamber rather than integrate a dose profile determined through thermoluminescence dosimetry. "$CTDI_{100}$" refers to the practice of using a 100 millimeter long ionization chamber either in the center hole of a phantom or in any of its peripheral holes to measure a value of CTDI integrated from -50 millimeters to +50 millimeters irrespective of the slice thickness T. Although the ionization chamber is contained entirely within the acrylic phantom, $CTDI_{100}$ usually refers to dose to air, not dose to acrylic as in the FDA definition.

A variant of $CTDI_{100}$ is what is called the "weighted" CTDI, abbreviated "$CTDI_w$," and it is based on a combination of values of $CTDI_{100}$ measured in the center hole and in the peripheral holes. This combination approximates the $CTDI_{100}$ averaged over the entire central plane of the phantom. Another variant, the "volume" CTDI is being introduced in an amendment to the current international manufacturers' consensus standard covering the radiation safety of CT equipment.

I'm going into such details because I want to point out the bottom line really. The bottom line here can be broken into two parts. First, variant quantities of CTDI that are either more easily determined, or of broader generality, or of more utility, have by and large replaced the FDA definition of CTDI for most practical purposes. Second, as a result of this proliferation of non-standardized terms, there is confusion amongst CT system users about precise definitions of CTDI values, especially for values displayed by some CT systems.

Possible amendments to the current radiation-safety performance standard would require particular technical features for CT equipment.

Although requiring such features through a mandatory standard applicable to all new CT systems conceivably guarantees the largest and most systematic dose reduction on a population-wide basis, there are a number of associated issues that demand careful thought before we undertake such change. We seek your comments, ideas, and questions on any aspect of what is being suggested. The initial focus of the work group effort is on three possible features - display and recording of standardized dose indices, automatic control of X-ray exposure according to individual patient thickness, and X-ray field-size limitation for multi-slice systems.

This amendment would require each new CT system to provide users with options to display and record one or more dose indices for every patient's examination. The dose indices and related terminology would be standardized through formal definition in the regulations.

This amendment would enable an aspect of facility quality assurance that today is feasible only with extra effort or through features available on just some newer scanner models. The basis of this quality assurance is the use of what

are called “reference dose values” as norms to which individual examination doses could be compared. If reference values are exceeded, facilities could follow up anomalies by looking at possible problems to see if exposures could be reduced without compromising image quality. A reference dose value corresponds to the 75th percentile of the distribution of measured dose values for particular radiological procedures. Reference values may be generated based on a facility's own records of dose distributions for various CT exams or based on regional or national dose distributions.

The concept of reference dose values, also called “reference levels”, was introduced in the United Kingdom about ten years ago and is being adopted throughout Western Europe. It is being introduced into the U.S. by the American College of Radiology with the aid of a task group of the American Association of Physicists in Medicine. For example, the ACR requires facility audits of dose values for comparison to reference levels in its new CT accreditation program. There is no question about the technical feasibility of simpler versions of such displays because they already are

available on some of the newer CT models, albeit with ambiguous definitions.

We assume that the systematic use of dose-index display or recording in a facility audit program could reduce patient CT dose on average on the order of 15 percent. This projection is based on the range of dose reduction observed between 1985 and 1995 in the United Kingdom for modalities other than CT, in a period before particular indices of patient CT dose were introduced.

There are several prospective indices of patient dose that could be displayed and recorded for the purpose of dose audits. For the two indices described in this slide, equivalent quantities are recommended in quality criteria guidelines published by the European Commission, although not quite with the same nomenclature as used here.

In the first amendment to the second edition of the International Electrotechnical Commission safety standard for CT equipment, the "volume" computed tomography dose index is introduced. It is based essentially on the weighted CTDI, which is a weighted sum of $CTDI_{100}$ measured in the central and peripheral holes of an

acrylic phantom. For axial scanning the denominator in the expression for volume CTDI is ? z/nT, the ratio of the table increment per rotation to the total thickness of tomographic sections imaged. In axial scanning the volume CTDI is essentially what's known as the "multiple scan average dose", abbreviated "MSAD". "Pitch" is the analogous denominator for spiral scanning. The important point here is that these denominators in the expressions listed account for modifications to the weighted dose index arising from possible gaps between multiple scans or their possible overlap for examination protocols that may differ according to the particular exam being performed. This accounting makes the volume CTDI more sensitive to differing examination protocols than either $CTDI_w$ alone, or $CTDI_{100}$ alone, or the FDA regulatory CTDI.

Another possible index for dose-display and recording is called the "dose-length product", and it may hold more promise than the volume CTDI. Dose-length product is simply the product of the volume CTDI and the length of the irradiated volume. Here is its chief advantage: Because the length of the irradiated volume depends on the region of the body being studied, different

examinations will be associated more uniquely with characteristic values of dose-length product than with values of volume CTDI.

This result is evident from the table on the left which compares values of volume CTDI to those of dose-length product. The dose-length product values are relatively sensitive to differences in exams, whereas for the kinds of exams listed here, volume CTDI is practically constant between 30 and 35 mGy. The implication is that facility audits of dose-length product could be exquisitely sensitive to anomalously large doses for each different kind of examination. Each kind of examination could be associated with its own unique distribution of dose-length product values.

Another point in favor of the use of dose-length product is that it is approximately proportional to the total energy imparted and is therefore a better indicator of radiation risk than is the volume CTDI. Using anatomy-specific coefficients derived from computer simulations, one can estimate effective dose from the dose-length product, and effective dose is the closest indicator we have for overall radiation detriment. It is my understanding that one manufacturer

already displays values for effective dose on newer CT models in Europe.

Of the three technical areas that we are considering, probably the largest dose reduction, at least for thinner patients, would be brought about by requiring every newly manufactured CT system to provide the capability of automatically adjusting the amounts of X-ray emissions to those needed to image particular patient anatomy. In other words, as the X-ray beam probes a thinner portion of the anatomy which would not require as much radiation as a thicker portion would in order to reach the detectors, the CT system would automatically reduce the average tube current, or voltage, or some combination of radiological variables to spare that thinner part unnecessary dose.

And conversely, when the beam encounters thicker anatomy, the CT system would automatically increase the tube output to levels needed for adequate visualization. An automatic exposure control system offers a technical answer to facilities where for practical or clinical reasons it is not the practice to change manual techniques on a patient-by-patient basis let alone

re-adjust techniques within a single patient exam. With an AEC system in place, the presumption is that pediatric and thinner adult patients would receive lower doses than thicker patients.

A number of different approaches for modulating X-ray tube output are available on newer scanner models, and these approaches span a range of technical complexity. For example, at one end of the range are systems that offer recommendations of specified technique settings for tube current-time product and tube potential that the user may choose to apply. Such recommendations are not automatic adjustments per se, but they are based on anterior-posterior and lateral scan projection radiograph data.

Scan projection radiographs are the scout views obtained prior to regular CT scanning. At the other end of the range of approaches to AEC is truly automated, continuously updated tube-current modulation in three dimensions based on measurements of X-ray attenuation at the corresponding angles of the previous rotation. In between these two extremes are several other algorithms offering, for example, automated tube-current modulation axially only for various image

qualities that may be selected by a user.

The figures in the slide depict how emissions would vary according to patient sizes in three dimensions. On the left is a cross section of the torso in the x-y plane, and the thickness or thinness of each red arrow corresponds to the relatively greater or lesser amount of radiation needed for reconstructing an image as the X-ray tube rotates around the z axis. Not only is there tube-current modulation for the x and y dimensions, there is also modulation corresponding to changes in average anatomical thickness along the z axis as the table moves. The graph on the right shows how the tube current is reduced or increased by this additional current-normalization factor that accounts for the average anatomical thickness which the fan-beam slice encounters along the length of the patient. For example, the X-ray tube output would be relatively small when the patient's neck is passing through the fan beam, but increases rapidly when the shoulders are in the beam and decreases as the beam probes the lungs. Calculations and measurements suggest that use of a sophisticated automatic exposure control system could reduce patient dose by approximately 30

percent compared to systems where the techniques are set manually.

We are concerned that a number of different multi-slice CT models produce images with a technologically inefficient application of radiation. This inefficient technology has been dubbed “over-beaming”.

The two figures represent a comparison of the spatial distributions of radiation incident along the length of a patient. The figure on the left depicts the distribution for a single-slice CT scanner, whereas the one on the right corresponds to that of a multi-slice CT scanner. The CT system represented on the left produces one image associated with a single slice, while the model on the right can produce four images simultaneously, each associated with a thinner slice. In each figure the gradient in area and intensity of shading from dark red to light pink is a schematic representation of the falloff in radiation exposure from the central umbra of the collimated X-ray field to the peripheral penumbra. On the left, a single detector, indicated by the green rectangle, captures essentially the entire radiation distribution. On the right, however, the system of

four detectors captures only the radiation of the umbra region.

The total width of the tomographic section imaged - 5 millimeters in this example - for the slice associated with the one image produced on the left is equal to the sum of the widths of the four 1.25-millimeter wide slices respectively associated with the four images produced on the right. In other words, in either figure the amount of visual information that can be used for image reconstruction is approximately the same, and in fact in the case of the multi-slice CT system, a user could elect to trade off the resolution offered by four adjacent 1.25-millimeter wide slices for a single 5-millimeter wide slice with relatively less image noise than in each of the thinner-slice images.

Here's the important point in this comparison: Although the amount of radiation applied to construct one image with the single-slice scanner or to construct a set of images with the multi-slice system is the same for each configuration, for the multi-slice CT system the radiation distribution is much wider than that of the single-slice system.

Why? Multi-slice CT imaging requires that radiation incident on the patient be consistently distributed across each of the separate areas subtended by the detectors. Such consistency can be achieved by opening up the z-collimation of the source radiation so that only the most spatially uniform region of the X-ray field, the umbra, is subtended by the detectors. I should point out that when that occurs, the spatially varying penumbral regions are excluded from the detectors. Furthermore, since the X-ray focal spot tends to wander around spatially, multi-slice models broaden the umbra by opening the collimation even more to compensate for X-ray source excursions. In the example depicted by these figures, the width of the z-collimation for the multi-slice system is 15 millimeters versus 5 millimeters for the single-slice system.

The problem of consistent spatial irradiation is not encountered in single-slice systems because the single detector is longer than the extent of the incident radiation, and it simply integrates the whole distribution incident. However, multi-slice systems are not efficient users of radiation in this sense: All of the

radiation that falls beyond the spatial extent of the detectors is not used by the detectors for image construction, but it is nevertheless incident on the patient, and it contributes to the dose.

To mitigate the inefficient use of radiation in multi-slice computed tomography, we suggest consideration of an X-ray-field-size limitation. Such an amendment would require that all new CT systems be capable of automatically limiting field sizes to those no larger than needed to construct multi-slice images.

Several technical approaches to enable such limitation have been patented, and one in fact has been implemented. The approach implemented uses some of the X-ray detectors lying beyond those capturing the clinically useful signal to track the wandering of the penumbral regions of the X-ray field and feed back instructions to motor-driven collimator cams to readjust their positions. Tracking and updated instructions are done in real time to maintain the narrowest needed umbra incident on the detectors. This system is represented by the figure on the left. The X-ray field borders demarcated by dashed lines are set by the collimator cams - also indicated with dashes -

for an initial position of the X-ray source so that the umbra is subtended by the clinical-signal detectors.

As the X-ray source wanders to the right, other detectors which are not depicted here pick up the movement of the penumbra and instruct the collimator cams to re-adjust their positions to those indicated by the solid lines. The result is that the umbra remains subtended by the clinical-signal detectors. Had the collimation position remained unchanged, there would have been an inconsistent spatial distribution of the X-ray radiation across the clinical-signal detectors.

The chart on the right represents two multi-slice dose profiles measured in a head phantom on the same CT system. For the same 5-millimeter wide imaging-sensitivity profile, the dose profile in black is obtained when there is no tracking and collimation-update system, whereas the dose profile in fuchsia is obtained when the tracking-update system is activated.

It is evident that the non-tracking dose profile is approximately 50 percent wider than the tracking profile. All of the radiation represented by the difference between the two profiles would

correspond to radiation which is incident on a patient, contributes to the dose but is not used to construct images. Data suggest that the kind of X-ray-field size limitation enabled by tracking and collimation adjustment could reduce dose in multi-slice CT systems on the order of 30 percent.

I will present quantitative projections of benefits that could result from the relative amounts of dose reduction associated with the possible implementation of amendments to the Federal radiation-safety standard in each of the technical areas just described. The principal benefit would be a population-wide reduction in morbidity and mortality associated with avoidance of cancers produced by CT radiation.

Projections are based on preliminary estimates of the current annual CT dose in the United States derived from the 2000-2001 N.E.X.T. survey. The survey results indicate that the total number of CT exams annually is approximately 58 million, where 79 percent of all exams are comprised of scanning in six anatomical regions or combinations of regions - brain, abdomen-pelvis, chest, abdomen, chest-abdomen-pelvis, and pelvis alone. Approximately 29 percent of all CT units in

the U.S. can do multi-slice spiral scanning, a remarkably large percentage since this technology was introduced to the market in 1998. The effective dose average for the six exam regions is approximately 6.2 millisievert, and the product of this average and the number of exams corresponds to a collective annual dose of approximately 360,000 person-sieverts per year.

If all CT equipment were to include the technical features just proposed for consideration as mandatory standards, then based on the relative dose reductions and the collective dose attributable to CT, one can estimate an annual collective dose savings of 193,000 person-sieverts per year; 54,000 for dose-index display and recording in a quality-assurance program, 108,000 for automatic exposure control, and 31,000 for X-ray-field size limitation in multi-slice systems. All of these values are uncertain, and they're based on a number of assumptions detailed in the slides, references, and notes.

For an annual collective dose savings of 193,000 person-sieverts, on the order of 8,700 radiation-induced cancer mortalities are projected to be avoided per year beginning 20 years after

each annual collective exposure. The yellow shading is intended to highlight the uncertainty in this projection which is based on an extrapolation to the CT-dose region of a mortality risk estimate derived from larger-dose epidemiological data. Other methods of extrapolation could yield higher or lower estimates of the number of radiation-induced cancer deaths, and it is even possible that the estimated dose savings would not result in any avoidance of cancer death at all. In the United States in the year 2000, the annual number of deaths linked to cancer from all causes not specifically associated with radiation is approximately 550,000.

There would also be a significant benefit in the pecuniary savings associated with societal willingness to pay to cover mortality risk. Economists have estimated that society pays on the order of $5 million per year per premature mortality that might otherwise be avoided.

Will there be amendments to the CT radiation-safety standard? Here are the initial steps in this process. We've come up with a framework for analysis that will lead to what is called a “concept paper” for amendments which will

be the basis for CDRH decisions on how to proceed.

This slide represents a framework for analyzing prospective technical areas with respect to issues that need to be addressed in decisions on how to proceed. In the block on the right, the region shaded in green lists the technical areas summarized in this presentation, and the region shaded in pink lists areas where we have an interest that is deferred for the time being. The yellow-shaded block on the lift lists some general categories of issues - technical feasibility, impact on clinical aspects such as efficacy and frequency of utilization, harmonization with international consensus standards, CDRH resources required to develop test methods and to incorporate the administration of new rules in a compliance program. The arrows indicate that in principle each of these issues can be applied as a basis of assessment to each technical area under consideration.

We would like to hear your thoughts about any of these issues. Although the equipment features that I've discussed today may all be technically feasible, there remain a number of particular questions outstanding. Here are a few

examples: First, for the purpose of display or recording in a quality-assurance program, not only would we have to select a representative index of patient dose, we would need to specify whether the dose index could be based on average values for a system determined by manufacturers for all models of scanners or whether it must be specific to the particular unit actually used in a facility. Should the dose index displayed or recorded be based on real-time measurements made during actual patient examinations? How would the index represent values in an automatic exposure control mode? Parameters based on CTDI may not be good candidates to represent skin dose, particularly for CT fluoroscopy. What is a good index for skin dose? What impact might a dose-index recording capability have on practice and use? Would there be any inhibitions fostered by the possibility of associating recorded values with patient medical records?

Second, with respect to automatic exposure control, in addition to specifying what kind of technological approach is best, perhaps the key question is how to define the optimal amounts of radiation needed by the detectors for particular

imaging tasks. These amounts would effectively set the points of detection equilibrium driving the modulation of emissions from the X-ray source according to patient anatomy thickness. Should standards be set to optimize detection? Who should set the equilibrium points and how would that be done? By manufacturers? By radiologists? By FDA? Philip Judy, a prominent medical physicist, has posed a related question: If automatic exposure control reduces dose to thinner patients on average, would it on average increase dose to thicker patients? The answer is not obvious.

Third, a primary challenge in developing an amendment for X-ray-field-size limitation or for automatic exposure control and most likely other areas as well would be how to prescribe performance standards-not design standards-forward-looking enough to transcend limitations that might be present in current technological approaches.

In conclusion, an FDA work group has identified several areas for possible development of mandatory CT-equipment radiation-safety performance standards. The initial focus is on technically feasible features that would reduce

patient dose - dose-index standardization, display, and recording, automatic exposure control, and X-ray-field size limitation. Were these features implemented on all CT systems, the projected collective dose savings in the United States would be approximately 193,000 person-sieverts yearly.

The work group has established a framework of issues for analysis that would be detailed in a regulatory concept paper for decisions on how to proceed. In the development process we need input from industry, professional and other stakeholder groups, the Conference of Radiation Control Program Directors and States, as well as TEPRSSC. Our time line for the initial stage of this process is the completion of a concept paper by the end of this year for CDRH review and decision making and a follow-up briefing for TEPRSSC next year. Thank you for your attention.

CHAIRMAN ROTHENBERG: Thank you. I think we can proceed with questions and comments from the Committee at this point. There are a number of concerns and questions I had. First of all, when are the results of the N.E.X.T. survey going to be published and where will they be

available?

DR. STERN: The "when" is problematic. There are preliminary results available right now on-line. The FDA CT web site contains the reference as a URL link. The definitive results of the survey might not be available for another year. We would publish those in the journal Radiology.

CHAIRMAN ROTHENBERG: Okay. Also with regard to the automatic exposure control, this would be potentially a device which would vary the exposure rate depending upon the thickness of the patient and the particular projections. But each of the manufacturers has a standard technique which they present with their devices. With automatic exposure devises in radiography, at least in screen-film radiography, the main technique about which the variations are made is determined by the optical density produced on the film.

In CT and other digital devices, we don't have that type of limit to guide us. Has there been any effort to determine how the manufacturers arrive at their techniques because each manufacturer for each type of machine may actually have for their standard technique a different dose which they present in their

literature?

DR. STERN: Well, that is the key question that you've raised about where to put the "set point," as it were, about which the radiation emissions are modulated. I think there's work going on generally in the community. I can't point to specific papers about it. It's a question that we have to think about in developing such a performance standard.

CHAIRMAN ROTHENBERG: Yes, John.

DR. SANDRIK: Way back on the first page of your presentation you mentioned balancing lowest dose and best image quality or something related to image quality, yes, lowest dose for the best image quality practically achievable. Then the bulk of the rest of the paper I think maybe until you got to the part about equilibrium points or something concentrated on the dose aspect with very little regarding the image quality.

I think particularly as Dr. Rothenberg brought up, when you get to the AEC performance some measure of image quality is going to be very critical in deciding how this system operates and what are its limits. I think that ought to be brought into some of this concept, at least in a

concept paper, for the the limits. What we see right now is just low-dose to no-dose CT is the only way to go because the only benefit is reducing cancer mortality. We don't see any sort of lower limit at which point the image becomes unusable. I think more effort would need to be put in towards that kind of work.

DR. STERN: Certainly we're very sensitive to the image quality. Image quality should I think have a primary role. These are issues that I've mentioned in the presentation. We would certainly consider the importance of image quality and how to adjust those accordingly for any kind of concept paper. That's our intent.

CHAIRMAN ROTHENBERG: Yes, Michele.

MS. LOSCOCCO: You indicated that the survey results were preliminary and on the web and will eventually get published. Does that include the work you're doing on the handbook? When would those doses be out?

DR. STERN: With respect to the handbook, there's no information on the web and there aren't preliminary results. The handbook project has been going on for a while. It's been deferred for a while for other priorities. There's

always a hope to get it done within a year. I can't give a definitive date for that. We want to work on it. We're working on it. We've done a lot of work on it. We'll get it out when we can.

MS. LOSCOCCO: Because I guess my thought process is I'm not sure where we stand with axial versus multi-slice. If we had that handbook that identified some of that, we might be able to get a handle on what kind of dose limits we wanted to set.

DR. STERN: It's not our intent to set regulatory dose limits per se. None of the technical features that we talk about for the amendments would set a limit on dose.

CHAIRMAN ROTHENBERG: Yes, Rob.

MR. PLEASURE: You begin the paper by saying that your concerns emerged as a result of the interplay of clinical practice and the technical aspects of CT. Then you identify as one of the major problems in the beginning the asymptomatic self-referrals.

I'm just speaking as a citizen. We watch television and see ads for CT with tombstones and all sorts of promotion of this. Working people go in and they get this perhaps without any

referral as you suggest in perhaps very large numbers. My sense is that your recommendations for change relate to recording and technical requirements of the equipment and don't touch this major problem of asymptomatic self-referral.

I know there are limitations as to the scope of this Committee. I am troubled that a central issue that you've identified may be only indirectly dealt with by your recommended changes. Isn't there authority under some of the enabling acts to do something about what may appear to be a defect because of its usage in this particular device? In other words, it's being used for a purpose that has no value in creating significant risk. No value at least in the reported literature. Why have you been so conservative in your recommendations?

DR. STERN: The approach that we take stems from our understanding of our authority under the Federal law, the Radiation Control of Health and Safety Act. One aspect of that act is to promulgate standards for equipment really. It's an equipment-based approach. It doesn't really give us authority on the use of the equipment.

We can't direct facilities on how to

use the equipment or not. Such authority is vested in the states. The states have that authority really. So our approach has been to do what we can with respect to equipment features or suggest that we might do with respect to equipment features to reduce dose. For the issue of asymptomatic referrals for whole-body scanning, we take an approach of providing information through our web site to alert people to the issues involved and to the problems involved with it.

MR. PLEASURE: Well, there is this reference in our manual and in the regulations to defects in an electronic product. One that does use radiation as an intended purpose has a defect if it creates an unnecessary risk of injury or fails to accomplish its intended purpose. In this particular case, I would for purposes of this discussion say that without any warning on the product itself that says that this product is not to be used for whole-body scanning in asymptomatic situations.

It's like when I was a child going into the shoe store and having my feet exposed to a fluoroscope just to fit my feet to the shoes. Here you have a product that's put out, advertised

aggressively and there's no warning label on the product itself that it is not to be used as you say for general screening and asymptomatic situations. So I would assert that under 21 CFR 1003.2 why is this not a defect in the electronic product? This is creating an unnecessary risk of injury in terms of your own report.

DR. STERN: I would have to pass on the definition of “defect” to people more familiar with how it's been used traditionally by CDRH, perhaps in the Office of Compliance who know about that. I can't specifically say how defect is defined.

Another point I do want to make though is that FDA or CDRH haven't taken a position that the practice of whole-body CT screening for asymptomatic individuals is bad and you should not do that. I think such decisions on efficacy are made by more expert groups, for example, the U.S. Preventative Services Task Force. What we're doing is we're trying to provide information about our concerns and about the possible risks and leave it up to individuals to make the decision for themselves.

MR. PLEASURE: Well, as a Committee Member I think it would be useful for us to have

more information about the application of the particular regulation that I referred to and whether or not with other enabling legislation we can make recommendations that connect the technical aspects of the piece of equipment to actual utilization, the interplay as you say of clinical practice and the equipment itself. If we can't touch that, then it seems that the scope is far narrower than I thought it was now after two plus years on the Committee.

CHAIRMAN ROTHENBERG: I think Dr. Suleiman would like to make a comment on this also. I would like to congratulate the Center on the web site that they did put up because I do think it provides a lot of very valuable, basic and advanced information for both members of the public and also experts in the field. So if people get to that web site I think they will be very heavily aware of the risks as opposed to what the minimal benefits might be from some type of situation. Of course that doesn't address your question, but it's there. The question is how to make people aware to read it.

DR. SULEIMAN: Okay. Before I hand off to Tom Shope as well, we look on this law as a regulatory tool. I think we've been focusing on it

because I think it's something that maybe we and we only can do, the FDA, and there are things to do to facilitate the process.

X-ray systems are medical devices and prescription devices. We allow them to be used only under the prescription of a healing arts practitioner unlike the foot fluoroscopes, unlike the people scanner that will come up this afternoon. Physicians are allowed to use not only drugs but other products off-line other than its intended use. There's a strong medical practice issue here that evades this specific regulatory law. I think we've looked at some of the other options.

We came up with the pediatric advisory. This Committee recommended that last year. We came out with an advisory alert to that effect. The web page which is extremely extensive hit the streets several weeks ago. There was an awful lot of thought and discussion and whatever. We took a very educational approach with that.

I'm throwing some of those factors out. We've weighed them and argued and developed some strategy. I think Tom you can probably discuss it in a little bit more detail.

DR. SHOPE: Tom Shope from the Office of Science and Technology. Actually I was going to stand up and address this issue of the "defect." The "defect" there has to do with a defect in the performance of the equipment. Our CT systems that are doing whole-body scanning are working as designed. I don't know what defect we would address there to get at from that standpoint. It's really a defect related to the emission of X-rays that the part of the regulation and law addresses. I don't think we see a way there to address this issue of use of a device being a defect in the device itself. So that was the comment I was going to make.

I'm a little bit out of my field in terms of getting into the legal issues. I think though our General Counsel and other people in compliance would agree that that's talking about a defect with regard to how the equipment actually operates, performs - emits or doesn't emit radiation when it should or shouldn't, as opposed to how the equipment functioning as designed is being used.

CHAIRMAN ROTHENBERG: Thank you. Yes, Maureen.

DR. NELSON: I want to make a comment and then I have a question. My comment is that I agree that right now there isn't any evidence to support the use of screening CT to cardiac disease or cancer or that sort of thing, but that isn't to say that at some point that it doesn't. I think we have to be careful to not slam the door completely on this use, although I would argue that this sort of use should only be done in controlled clinical trials at this point in time.

The question that I have follows on Mr. Pleasure's question. That is that we did put out an advisory last year for pediatric use of CT. It seems to me could we not extend that advisory to this not only putting up a web site, but my understanding is that you actually sent letters out or something like that. Could somebody tell me what we did with that pediatric advisory and what that consisted of?

DR. STERN: It was a public health notification. It was sent out to people physically. It's on the web site as well.

DR. NELSON: Who are the people you sent it to?

DR. STERN: Radiologists, hospital

administrators, radiation risk managers at hospitals.

DR. NELSON: Couldn't we do the same with this?

DR. STERN: What I'm suggesting is it might be premature to do the same. You'd have to describe the nature of the advisory. Is it that there might be a problem? There is a problem? It might be premature. Just as you've said right now that you don't want to close the door completely. It might take a while to evaluate the efficacy of screening exams.

DR. NELSON: It seems to me right now you could say that there is no good evidence that shows that these screens are beneficial and that physicians and these people you mentioned should be very cautious in recommending them or prescribing them.

CHAIRMAN ROTHENBERG: Yes. Basically what you are saying is to essentially put out some amended version of what's on the web site itself since it's already out there publicly making those statements. Why would this change anything?

DR. NELSON: Right.

CHAIRMAN ROTHENBERG: It would just put

it into very targeted hands.

DR. NELSON: Right. I'm not sure everybody reads the web site.

DR. SANDRIK: On another area of the dose indices, about 25 percent of your dose savings deals with the users making some notice of the dose indices, doing audits, setting up reference dose levels, but as you also pointed out the performance standards apply to manufacturers and not to facilities. What methods would you expect that you'd be applying to try to capture this 25 percent of dose savings when you really don't have a regulatory control over this group or I think you'd need to have that?

DR. STERN: We can only make recommendations to users on how to use such systems. The starting point, getting out the gate, is having a requirement that all CT systems provide the users with an option for a display and recording facility. Right now there is no such requirement. Most CT systems don't have any display capability right now. We're just looking at getting it off the ground. With respect to how the users actually implement it, that has to do with education and information and persuasion.

CHAIRMAN ROTHENBERG: Yes, Dr. Benson.

DR. BENSON: To address something along those lines, you've been mentioning that the CT dose display would be something that you'd want in new machines as they're manufactured. Is there any way we can encourage manufacturers to make a device that could be an add-on to existing machines? Only because the generation time for replacement of machines is eight to ten years, whereas the add-on generation can be anywhere from one to three years. Our dose savings could kick in perhaps sooner than might otherwise be.

DR. STERN: Well, what you're saying is true. It's just that our regulations are prospective. They're not retro-fitted to older equipment. If one believes that dose display is useful and one wants to promulgate a new rule or standard for dose display, then it's possible to encourage add-ons to existing systems as well. My impression is that CT equipment is replaced rather rapidly, at least recently.

CHAIRMAN ROTHENBERG: I'd just like to make another point. In terms of the dose display, it seems to me that in most cases since everything is already in a computer on a CT scanner, this

involves more of software development as opposed to hardware changes on the equipment itself, so it might possibly be easier to implement that then it would be on certain other types of X-ray equipment.

I have a related question to that. In terms of proposing the dose display on the machine, again because it's a computer, I would also like to suggest that there be a method for somehow recording and putting in some type of database this information because currently we have a situation with some of the fluoroscopy equipment where we have built into a number of newer pieces of equipment a dose display device which may come up at the end of the exam. However, on many of these pieces of equipment, and I'm not familiar with all of them, when the next patient is entered that information disappears.

There's no logging of that. That then means that it's incumbent upon the technologist or somebody else in the facility to record that information usually in some log book. The question is how do you deal with this information. It's all handwritten in a log book as opposed to being on a computer where it would be amenable to some type of analysis for arriving at reference levels and just

keeping track of certain patients that are getting many exams. So if there's a recommendation to have a display which is already present, as you mentioned, on many of the new scanners, that it also possibly be a recommendation to be able to keep the data.

DR. STERN: Thank you. That's an important comment. A recording feature is one of the aspects we would consider.

CHAIRMAN ROTHENBERG: Yes.

DR. BENSON: Another feature you might consider. We had talked about setting dose limitations and how that might not be a good idea. On the other hand, if you come out with recommendations that companies set them at a low level and make those default settings so that a patient who is put through willy-nilly, which unfortunately quite often the case in these high-throughput CT establishments, those people would not be unintentionally over-dosed. If anything, they would be unintentionally under-dosed.

And make it a conscious act to increase the dose to a level that would make an image that, say, the individual radiologist would want. Make that a conscious act so that it is perhaps one way

our Committee can be a little more effective in terms of reducing overall dose in making intentionally low recommendations so that image quality can be more carefully controlled on a patient-to-patient basis.

DR. STERN: Thank you for your comment.

CHAIRMAN ROTHENBERG: Yes.

MS. LOSCOCCO: Well, I guess along those lines I think there's some hesitation probably on the part of industry, on the part of the physics community that helps set up these dose recommendations and protocols that the radiologist is the one that eventually has to read that image and is the one that is held responsible for finding the data. That's kind of where I was going with my first question. You have to tie image quality to your limit or recommendation. How are you going to come up with that kind of range?

DR. STERN: I can't answer the question of how one would determine a set-point for an automatic exposure control system to modulate the emissions of that with respect to optimal image quality and minimal dose. It's something that's a research problem that has to be worked out, I think, over time.

CHAIRMAN ROTHENBERG: Certainly there is already in each manufacturer's specifications some index point of low contrast performance at a certain standard dose level. So there's certainly on the way to that position because clearly the low contrast performances are going to be most heavily affected by the dose setting.

DR. BENSON: Well, I would say that the Society for Pediatric Radiology has spent the last year on this subject and has a publication currently out of the summary of their efforts. They have come up with a dose schedule that seems to produce good radiologic images at much lower doses then have previously been used. If those could be adopted and adapted by the individual manufacturers as a baseline then in effect it will bring the radiologists back into the process of producing images where up until now they've been if not excluded at least ignored.

CHAIRMAN ROTHENBERG: Yes, Jill.

DR. LIPOTI: There are a couple of pieces of background information that are not in our packets that I think would assist this Committee in making recommendations. One is a copy of the FDA web site having to do with whole-body

scanning. Another one is a copy of the preliminary results of the N.E.X.T. survey which are on the web but which were not part of our background materials. A third one is some information from the American College of Radiology on their accreditation process which is not yet in place as I understand it but is anticipated for CT.

DR. STERN: Sorry. I believe it is in place, yes.

DR. LIPOTI: Well, people have applied but I'm not sure that people have been approved yet. But I think that we have to look at this whole approach to CT as a partnership. It's a partnership where the FDA has a significant leadership role particularly in providing for changes to the equipment so that the user can then be more intelligent in their use of this particular modality.

I would look to states as being the ones who would deal with medical practice issues and the prevention of unnecessary radiation exposures and could perhaps provide a requirement for a quality assurance program which is the thing that you need to make sure that all users then use the features that the manufacturers have built into

the system. It can't be approached as only FDA requirements. It has to be looked at as the total regulatory spectrum.

I guess as part of that though I would also look to FDA leadership to help identify the costs perhaps of some of the retro-fit that would be needed for a current CT to provide some information about dose indices for the user. Yes, states can write a regulation that would require retro-fit, but then each state is going to have to do a cost benefit analysis individually whereas perhaps in the course of collecting data from the manufacturers on providing these options on new machines you could also collect data on providing that as a retro-fit.

CHAIRMAN ROTHENBERG: I would like to just raise one other point in terms of at least the educational activities of the center. That is when I speak to radiologists they seem to be particularly in the recent years much more aware of the fact that the dose from the CT exams is higher in many cases than from certain other routine exams that are being performed.

However, I also hear that although many of the machines are in the radiology department and

they are performing the diagnosis and the radiologic technologist performing the exams, they don't necessarily control how often the exams are performed and on whom they're performed. They are often required to proceed with exams ordered by other physicians. I think this is an area where the other physicians may be routinely ordering exams, as with any other radiology exam, that may not always be necessary. I think it's important to make the rest of the medical community aware of the dose levels in CT exams.

Again I know there is web site information but in terms of getting to others, maybe targeted mailings to other medical societies for distribution to their members would also be a good idea to follow up on. This could lead to a significant reduction in dose just by preventing unnecessary exams being performed.

MR. PLEASURE: You've identified, Dr. Stern, through automatic exposure control and X-ray-field-size limitations and dose index standardization, display and recording, ways of reducing unnecessary exposure. Right now it's feasible as I understand it. The new models have this capacity in these three areas.

What I'm trying to understand is the interplay of this responsibility to identify a defect in old equipment let's say that does now, if I were to infer from this, it does have too large a field-size, too wide a field-size right now on the old equipment and it's possible to narrow it. There's no automatic exposure control so that we're creating unnecessary exposures right now with the older equipment. The professionals have limited capacity to identify the exposure.

So I have a piece of old equipment. I would just as a person on the street say the old equipment has a defect given the state-of-the-art. Why not use those remedies available to FDA for defective equipment to move toward reducing all these unnecessary exposures?

DR. STERN: Well, this is really a legal question. It's beyond my expertise to address how FDA could answer that question.

MR. PLEASURE: But I would argue part of the responsibility of this Committee is to look at the legislation that creates the Committee, the remedies that are available that are actually referred to in our manual, and to make recommendations as to not only the narrow issues

that are brought before us but also as to ways of dealing with it that are within the scope of FDA's authority, and this Committee's purview if I read the manual correctly.

CHAIRMAN ROTHENBERG: I just want to raise one point with regard to this specific issue that Dr. Stern hopefully can reply to. If I were to go right now and buy a CT scanner, could I buy one with automatic exposure control? I know there have been many papers and they are under development.

DR. STERN: Yes. I think you can. I think there are some systems that offer that feature.

CHAIRMAN ROTHENBERG: With an actual feedback type system as opposed to based on -- view.

DR. STERN: I believe so, yes.

MS. LOSCOCCO: They exist.

CHAIRMAN ROTHENBERG: I haven't seen one in operation yet, but I know they're coming. They're very limited at this point, but this is certainly something we should keep in mind for the future. Maybe we want to make a recommendation that they should evaluate again cost benefit for

this type of modification of older equipment.

MR. PLEASURE: Well, there is a cost benefit analysis at least in terms of on the benefit side the numbers of people who are currently being exposed and the costs associated with those unnecessary cancers that are caused. It's $5 million per person.

CHAIRMAN ROTHENBERG: But I think also in terms of cost, what would be the actual cost to the person using the machine to have the machine upgraded?

MR. PLEASURE: Well, one of the remedies available if you identify it as a defect if it rises to that level is to require notification to go out to everybody that's purchased this and tell them there are problems with the equipment that you're using. You could do much better. I mean, before you actually pull it off the market at least you could get the word out. Manufacturer notifies purchasers, dealers and distributors of a hazard and appropriate use until corrected is one of the identified remedies in the regulation.

CHAIRMAN ROTHENBERG: Certainly again --

MR. PLEASURE: That doesn't cost much.

CHAIRMAN ROTHENBERG: Based on Dr. Shope's previous statement, the definition of defect that you are raising is certainly different from the one that the Center uses.

MR. PLEASURE: No. I think I was speaking in broader terms before. Now I've focused on defects or limitations that have been identified in this paper on unnecessary exposures because of the width and possibilities of limiting that, and there were two other areas that I identified that the paper has identified that are limitations that are not present with the newest equipment.

So this relates directly to the unnecessary exposures by the equipment because technically it doesn't have the capacity of the newer equipment. These are meaningful distinctions because as identified by Dr. Stern, they're producing unnecessary exposures. Unnecessary because we have the equipment to avoid it.

I think this defect relates not only to manufacturer's failures in the manufacturing process but producing something specifically that's causing unnecessary risks and exposures that we can avoid. We should be using the best available and

safest technology.

DR. NELSON: I was wondering if you wanted to make a motion. The other thing I was wondering if it wouldn't be helpful to maybe have some legal people from FDA speak to this Committee about the issues you've raised.

MR. PLEASURE: Well, that's an interesting invitation.

CHAIRMAN ROTHENBERG: Why don't we just have a formal recommendation for the FDA to look at the law again and see whether this interpretation which is different from their previous interpretation is supported by the current --

MR. PLEASURE: Well, I would differ with you as to whether it's different from their previous interpretation. I earlier had raised a question as to whether the scanning, that is the practice of scanning in asymptomatic self-referred cases was in itself a defect. I'm not talking about that now. It was indicated that it was not the way technical staff understood the regulations. I'm now talking about a performance standard, that the older devices are producing unnecessary exposures that the newer devices that have been identified don't produce.

CHAIRMAN ROTHENBERG: But it's not clear to me. The older machines are potentially going to produce the same doses when proper account is taken by the operator for the size of the patient. This could be potentially addressed. At least a major aspect of it, not 100 percent of it could be addressed by the proper education of the user.

MR. PLEASURE: I don't understand that to be the case.

CHAIRMAN ROTHENBERG: Certainly for different size patients we could --

MS. LOSCOCCO: I think you're actually talking about two different things. You're talking about the collimation, the fact that the detectors in the multi-slice, the profile of the beam is extending past the detectors. You're talking about particular patient doses. Am I following you correctly?

MR. PLEASURE: Well, if you take a look at pages 11 and 12 which is the concern and 13 of the report that relate to automatic exposure control, inefficient use of radiation and field size with a patient, it ends with feasibility of using newer models that give this capacity. I

don't think people have the capacity when they're using it to get to this point. As I understand it, the equipment doesn't allow for limiting this unnecessary exposure in ordinary use. What I think a first level would be is at least the manufacturers to notify users and others to whom they've distributed equipment that the equipment is producing unnecessary exposures.

I would agree with you, Chair, that it would be useful to have some discussion as to the ways in which FDA uses this defect in electronic products to deal with uses of products that are no longer state-of-the-art. Why do we have to wait five or six years for the change to occur? Shouldn't there be some assessment of the damage that's being done right now that's feasible to avoid? Shouldn't there be a cost- benefit analysis of that as you suggest?

CHAIRMAN ROTHENBERG: Do you want to make a motion to that effect?

DR. LAMBETH: Perhaps I'm a little naive about certain aspects of implementation in this whole process, but there were several things I picked up out of your discussion that I would like to touch on just a second. One was your specific

recommendation was that the automatic exposure control would be an option, not a requirement.

DR. STERN: The automatic exposure control would be an option for the user to use. The user could use automatic exposure control or a manual technique at the user's discretion, but the requirement would be that the CT unit have the capability of doing automatic exposure control.

DR. LAMBETH: And that would be for future machines.

DR. STERN: Yes.

DR. LAMBETH: Not retroactively.

DR. STERN: Correct.

DR. LAMBETH: Which is what we're now discussing here. I tend to hesitate to use the word "defect" because I tend to think of the word "defect" as meaning something that has gone wrong as opposed to a deficiency in old equipment which was designed that way to start with.

The other aspect of that is the display index. Having that is only an educational aspect. It's not something that suddenly changes the amount of exposure that a patient gets unless the operator chooses to use it in some intelligent way.

DR. STERN: That's right.

DR. LAMBETH: So implementing that actually seems, I agree, more like a software issue than a hardware issue. But I don't know many of these machines so I couldn't really say that for sure, but I know how some of the machines are probably built. In terms of the automatic exposure control, there's an assumption being made in point of fact the operators are over-exposing the patients either because they're in a hurry, they want to guarantee a good image every time or they're not well educated about the benefits and trade-offs.

So I'm sure the study was done conscientiously that predicts the savings and exposure, but there are guidelines the manufacturers have that says this is what the exposure should be, I assume. They would put that with their products when they were selling their product. So I was curious about this summary number about the savings, not so much about how to operate the machine as opposed to how the machine is being misused to get this number.

DR. STERN: The savings in dose, you're talking about the percentage dose reductions.

DR. LAMBETH: Right. You're final

summary.

DR. STERN: The final summary is based on the percentage dose reductions that are based on a number of assumptions detailed in the notes. The current number of exposures as determined or as inferred from preliminary data of the N.E.X.T. survey, that's where those numbers come from. Am I not answering your question?

DR. LAMBETH: I guess it's just an unknown on my part. I'm just questioning it and probing you. Forgive me if I do that a little bit. In actual operation, we're making an assumption that the operator over-exposed the patients compared to what an automatic exposure process would do.

DR. STERN: Those numbers for automatic exposure are based I believe on a couple of papers detailed there for measurements really. You could be right in the sense that on average if operators were using their current systems ideally now, they would be based on technique charts where they would set their technique settings for the examination and for the size of the patient that they are examining. We don't know how all operators are doing with respect to that. So there is some

assumption that it could be better through an automated exposure control system.

DR. LAMBETH: Any system that would have automatic exposure control I would assume the operator would have some adjustments on that or some ability to adjust it or as you said turn it off entirely.

DR. STERN: Yes. The operator could use the manual techniques that an operator uses currently. They're not obligated to use the automated exposure controls.

DR. LAMBETH: I would think there would be a high propensity to always over-dose the patient to make sure I got a good image.

DR. STERN: Well, part of the problem raised by Larry Rothenberg and John Sandrik had to do with how does one set an automatic exposure control system to give very good images and at the same time reduce the dose. That is a problem that has to be worked out.

CHAIRMAN ROTHENBERG: We have to cover several issues today, so I'd like to try to wrap this up. What I was hearing were at least three recommendations that maybe the Committee would like to proceed with motions on. One was just first of

all dealing with the current CT screening web site information to have that as a more targeted mailing similar to what was done with the pediatric and small adult information a year ago. I think that one would be able to deal with quickly. Can we have someone make a motion?

DR. NELSON: I'll make a motion.

CHAIRMAN ROTHENBERG: Okay. So basically the motion will be to take the information that's on the web site and distribute it to a more targeted audience similar to what was done with the pediatrics.

MR. PLEASURE: I'll second that.

CHAIRMAN ROTHENBERG: A second. Any further discussion of that?

MS. LOSCOCCO: Would that be to include beyond the radiology community I think was the intent?

CHAIRMAN ROTHENBERG: Yes. Any other? All in favor on the Committee of that motion?

(Chorus of ayes.)

CHAIRMAN ROTHENBERG: It looks like pretty much unanimous with that. That's certainly one recommendation. The other was just to follow through on Dr. Stern's request or point out that

they want to proceed with the regulatory concept paper with more complete analysis of the issues raised in his presentation. It sounded like we certainly want to proceed with all these issues. Is there a motion?

DR. LAMBETH: Well, adding to it that image quality be made a significant part of that concept paper which I don't think it was quite as significant in the presentation as you just mentioned.

CHAIRMAN ROTHENBERG: So do you want to make that motion?

DR. LAMBETH: I move that the concept paper go forth with the dose and image quality measures in terms of limiting dose to CT.

CHAIRMAN ROTHENBERG: Is there a second?

DR. LIPOTI: I'll second it, but I'm concerned about the time line which was given in the last page, page 19. The concept paper is to be completed somewhere around December 2002. Then there's to be an update for TEPRSSC.

At that point, I would assume we would be asked if we want to proceed to a Notice of Proposed Rulemaking. That could take if we follow

the fluoroscopy example three to four years before a Notice of Proposed Rulemaking gets out of the Agency. Then they'll be a 120 day comment period, response to comments received another two years to respond to comments. We're looking at maybe 2009 before we have final standards for the manufacturers. I'm very concerned about a time line that's that long. I would like to add to this motion a compressed time line which moves to the Notice of Proposed Rulemaking in 2003.

CHAIRMAN ROTHENBERG: Okay. Are you willing to accept that? Do you want to comment on that?

DR. LAMBETH: I guess I would like to see what the concept paper produces before we talk about producing rules from that and at least have the opportunity for the Committee to review the concept paper before that would go into a proposed rulemaking.

DR. BENSON: Well, certainly some kind of compressed time line might be in order just simply to keep up with the pace at which technology changes. We don't want to perpetually chase our own tails.

DR. LOTZ: I was also going to say that

it seems like encouraging a faster time line does not necessarily hasten questionable decisions or whatever because even in an NPRM there is all the comment time and so forth. FDA is not going to throw one out on the street without a great deal of internal and probably even some stakeholder deliberations and so forth. It would seem to me that there are safeguards built in the process even in working with it and trying to move it along quicker.

DR. LIPOTI: I'd like to speak to one more point about the need for that compressed time line. We're basing a lot of this on the N.E.X.T. survey data which I have seen. That survey data was collected in 2000 and 2001. It has been since 2001 into 2002 that we've seen the advent of these screening clinics. This N.E.X.T. data does not capture the number of people that are receiving these whole-body scans, asymptomatic individuals with self-referral.

We need to do something about the equipment. We need to do something about how the equipment is used. We need to do something to retro-fit previously purchased equipment. We need to do something to educate individuals about the

use of equipment. But the first step and the need for the FDA leadership is in setting something for the manufacturers to shoot for.

It's true that there are CT machines available that already have an automatic exposure control and some of these other features. But there's no economic incentive for an institution to purchase these unless there's a regulation requiring that they be purchased. So despite all of the best intentions of the radiology community and the medical physicists in recommending that these new features be purchased on the machines, it really comes down to bottom line. It costs more to buy something with an AEC or to have a dose-index readout which can then lead to better use of the equipment. So I think we really need to move forward on these three concepts.

CHAIRMAN ROTHENBERG: Well, is it possible for us to do more than recommend that the time scale be compressed? We're already at May. They're talking about having something in December.

DR. LIPOTI: They're talking about a concept paper. I want a Notice of Proposed Rulemaking commitment.

DR. SULEIMAN: Let me clarify. The

concept paper is an internal process. We don't even go forward unless the center decides that the concept is sound. I'm not 100 percent certain of this but I don't think it's necessary or essential to share it and therefore delay the process. That's our own internal safeguards.

We're running these proposals by you now. You could argue that we don't necessarily have to come in front of TEPRSSC again for this issue because when we go with the proposed rulemaking, everything is out there for everybody to comment on. So requiring another review by the Committee, we have people who probably enjoy doing that but I think it's not going to speed the process up. So I think we're trying to weigh that internally.

The other thing is if you want to get work done, you have to keep the task simple. I just beg you to try to keep the task clearly defined, the recommendations clearly defined and then we can probably act on them one by one. If you give us a run-on sentence, we're going to spend a lot of time arguing about what you really meant. I think we want a clear message from the Committee. If it means breaking up into three or

four very simple recommendations, we'll address them one by one.

MR. PLEASURE: Well, I would like to invite Dr. Lipoti to make a motion. She expressed my concerns better than I did.

CHAIRMAN ROTHENBERG: Okay. We have a motion to proceed with the schedule. It seems like there may be concern that maybe that's not the way to go at this point, that we should give more specific targeted time lines to actual proposed rulemaking as opposed to proceeding with the concept paper.

DR. LAMBETH: Is the motion written? Can you read me the motion?

CHAIRMAN ROTHENBERG: Well, I believe it was to go ahead with the concept paper as proposed by Dr. Stern with the addition of addressing the image quality issue.

DR. LAMBETH: And so you want to put a time line on that concept paper and then you want to add the other time lines.

DR. LIPOTI: No. Actually now that I know what the concept paper is I could ignore the concept paper. I want to go right to the Notice of Proposed Rulemaking. The internal workings of FDA

really don't involve me.

CHAIRMAN ROTHENBERG: Okay. But do we want to encourage them to go ahead with the concept paper and address the image quality in addition to anything else we're going to propose?

DR. LIPOTI: Maybe we should say we strongly endorse the framework which has been provided by Dr. Stern. We urge the inclusion of an image quality component. We strongly endorse FDA moving forward to proposed rulemaking in 2003.

MR. PLEASURE: I'll second that.

CHAIRMAN ROTHENBERG: I'm not a parliamentarian, so where do we stand with regard to our previous motion?

DR. SANDRIK: Withdraw the first motion.

CHAIRMAN ROTHENBERG: Okay. So given that second motion, is there further discussion on that?

(No response.)

CHAIRMAN ROTHENBERG: Okay. All in favor of proceeding according to the motion made by Dr. Lipoti and seconded?

(Chorus of ayes.)

CHAIRMAN ROTHENBERG: Do we need to do

more specific things with regard to that motion?

COURT REPORTER: You need to announce the results for the record.

CHAIRMAN ROTHENBERG: Okay. Can we have the vote one more time?

COURT REPORTER: Just say the result.

CHAIRMAN ROTHENBERG: Okay. It appears to be unanimous. It is unanimous. Okay. There was a further discussion about asking someone from the FDA to come back to us and tell us about the capability to proceed with recommending that older equipment which would be considered to have a defect or whatever the appropriate word is to also be addressed in the rulemaking. Did you want to propose?

MR. PLEASURE: I would propose that the issue be addressed in the proposed rulemaking, and that the proposed rulemaking explain the implications of this particular proposed rule to retro-fitting, replacing, repurchasing older equipment applies, how labeling is affected, that it is compliant with existing regulations would be affected. In other words, I would like to see the proposed rule embedded or framed in an explanation as to how this rule would be implemented.

CHAIRMAN ROTHENBERG: Are you talking about this rule in particular or in general?

MR. PLEASURE: Well, right now I'm just talking about this rule. I had expressed myself before that it would be useful when we took up these issues as Dr. Lipoti indicated before it would be good to see these in a broad regulatory framework so that we understand both state, Federal, and the various acts that affect our deliberations, how this all comes together and changes practice in the field.

CHAIRMAN ROTHENBERG: Could we just ask then for a reply on what is the authority to require retro-fitting of existing equipment to be in compliance with new regulations?

MR. PLEASURE: Yes. I think the proposed rules should deal with that issue. So that's as far as this motion goes. I'm not now saying that it must require retro-fitting. After you consider that issue, I may go beyond that and suggest that we also may want to recommend what we think the implications of this is for enforcement purposes.

CHAIRMAN ROTHENBERG: Okay. So for the moment we're asking for the proposed rules with

regard to CT that retro-fitting be considered.

MR. PLEASURE: Yes.

CHAIRMAN ROTHENBERG: Okay. Do we have a second for that?

DR. NELSON: I'll second.

CHAIRMAN ROTHENBERG: Okay. Any further discussion?

DR. SANDRIK: Just a couple comments. One point I think Dr. Stern brought up was that probably the oldest systems are mainly single-slice systems for which the collimation issue probably doesn't apply. The dose savings regarding collimation is mainly probably on the most recent two or three year old systems. I think some of those are probably being addressed retro-actively anyway.

The issue of AEC is probably not going to be easily implemented back on these systems, but in any case there is manual control. It's largely a matter of user education to take advantage of those controls. Even if AEC was retro-fitted on those systems, it's not required that they use it in any case.

What's the other one? It's the reference levels. It's largely a matter of user

education. I'm just not convinced that there is a lot of benefit in trying to retro-fit particularly the old systems where some of these things just don't apply to what the issues are raised in some particular cases, like the multi-slice.

CHAIRMAN ROTHENBERG: Well, we're asking them to consider this. After consideration they may decide how to proceed with that which may address the issues you've raised.

DR. LAMBETH: I tend to agree with the last comments a little bit because on page 16, the uncertainty statements that are delivered with respect to the projected benefits. If you can't be certain that there's any benefits, then it seems like you're creating a situation. If it's a requirement on old machines to retro-fit them, you're injecting a lot of cost and time and difficulties without any real understanding of the benefits. So if we're going to do a study on whether or not we should do that, I think we should really tighten up on these benefits that are going to be attained out of it so that you make a logical decision at the end.

CHAIRMAN ROTHENBERG: Isn't that normally a requirement?

DR. LAMBETH: But I'm saying tighten up on it. This is highly uncertain. You go through this and it could be that the numbers are way off.

DR. SULEIMAN: Well, I think the uncertainty error margin is basically just because of a lot of the atomic bomb data. That's just the best science there is. I think this is just your discussion on your motion.

DR. LAMBETH: But there must be a lot of uncertainty in the aspect of how much abuse there is to the machine in terms of just negligence of the user as opposed to yes I always over-expose the patient because I want to get a really good image and I'm not going to back that off even if I have automatic exposure control. I don't know how you get your hands on that, but it's a crucial aspect of the process.

MS. FAHY-ELWOOD: I would just have a comment with all due respect, that is separate of the motion that was made. The motion is that as part of the process of proposed rulemaking that FDA consider that all old machines be brought into compliance with the new rule. So that could all be included in the discussion certainly within the rulemaking discussion but as far as the motion

goes, I don't know. The motion itself, are we voting on the motion, I don't know if it applies.

DR. LAMBETH: Well, I don't know what it means to consider retrospect. It seems to me part of the consideration process should be is it really worthwhile because I think it probably represents a lot of trouble for people to implement something retro-actively and to older machines.

DR. SULEIMAN: Again, I'm trying to clarify here. The way I see it is we're going to go back and we're going to look at the legal authority. If in fact forget historically, traditionally, we grandfather in the old equipment, do we in fact have the authority to retro-fit and make this applicable to existing older equipment? I think that's a yes or no answer by our legal staff.

I think the second issue of whether we go ahead or not on that is an FDA decision. I guess once we find out we can do that then we'll make a separate decision. If we don't have the authority, the decision has been made for us. If we do have the authority, then I think we'll have to do a more detailed economic analysis and benefit and find out we do have quite a bit of information.

There's no other such information out there, but there's clearly a lot of information we don't have access to.

How much more science? How much more data? That's why you're here, to help balance and give us your opinion. Clearly we're not coming in out of the blue on this thing because if you look at our CT web site and you look at all the other organizations, professional societies, they have all weighed in. They've all stuck their neck out and expressed similar concerns. We're clearly not doing this by ourselves. We're clearly part of a large concern about this issue.

CHAIRMAN ROTHENBERG: Okay. I think we do have to move along. So can we now take a vote on this most recent proposal? All in favor?

(Chorus of ayes.)

CHAIRMAN ROTHENBERG: Opposed?

(No response.)

CHAIRMAN ROTHENBERG: Okay. It's one opposed and the rest in favor.

DR. SANDRIK: Two opposed.

CHAIRMAN ROTHENBERG: I'm sorry, two opposed. Okay. So we had how many in favor? Let's just get the count again. Ten in favor and

two opposed. Okay. I think we then should take a short break at this point. Then we would like to consider the next issue before our lunch break. Let's make this short. About a ten minute break and then we'll reconvene at 11:10 a.m. Off the record.

(Whereupon, the foregoing matter went off the record at 11:00 a.m. and went back on the record at 11:14 a.m.)

CHAIRMAN ROTHENBERG: On the record. Our next item of business is generally labelled Sunlamp Products. We're going to have a presentation by Dr. Howard Cyr, but we're also going to have several speakers in the Open Public Hearing part in this. Dr. Suleiman is just going to read the list. We'll start with Dr. Cyr's presentation.

DR. SULEIMAN: All right, yes. The four public speakers, I just want to make sure we didn't leave anybody out. This is the order of their appearance. It will be Don Smith, Joe Schuster, Steve Mackin, and Bob Levin. When the public speakers speak for the record not only say your name but also your affiliation.

CHAIRMAN ROTHENBERG: Okay. So now,

Dr. Cyr, please proceed.

DR. CYR: Good morning. My name is Howard Cyr. I'm with the Office of Science and Technology in the Center. I guess I have to speak really close to this.

CHAIRMAN ROTHENBERG: Are we okay on that microphone?

(No response.)

DR. CYR: I'm going to speak about possible amendments to our Sunlamp performance standards. I want to give you just a very brief background. This started about four years ago. Several things happened. Number one, it's been some 15 or 16 years since we looked at the performance standard. Science has changed and we wanted to look at our standard in terms of the changes.

The other significant event was a petition, actually two petitions, but the main one from the Academy of Dermatology asking us either to ban sunlamps or if that couldn't be done to strengthen our warnings and educational efforts. We replied to them that we were not having any intentions of banning sunlamps but we would work toward the second request on stronger warnings.

I spoke to TEPRSSC two years ago. In that time, we presented five possible amendments to our performance standard. We had looked at this in some detail, and our assessment in the year 2000 was what we were presenting to you at that time was a non-controversial. In reality of course, things erupted rather quickly, and there were major concerns from the affected industry. This became a matter of controversy in a quick period of time.

I'm going to highlight here two of those controversial proposals. At the time, we thought it would be a good idea to incorporate a recommended exposure schedule. That's how much dosage somebody should get to produce and maintain a tan, how to build up to the tan and then how to maintain the tan, putting that recommended exposure schedule into the standard per se.

As an interim measure, we proposed putting the existing performance standard in realizing full well that it was one of the items that needed revision based on new science. You TEPRSSC people wisely told us why incorporate something you already know is outdated into a standard. So that was one of the items that turned out to be controversial and told us not to go

forward with.

The second one was to incorporate a non-melanoma action spectrum in addition to what we were using at the time, an erythemal action spectrum. The non-melanoma action spectrum is used internationally to classify lamps. We were thinking along those same lines. At the TEPRSSC meeting two years ago, you told us our use of this new action spectrum seemed to be rather premature and that we really hadn't gone through all of the various steps as to how we were going to use it, and why don't we go back and study this a little more before we come back to you with that particular proposal.

What you did instruct us to do was to go and talk with the stakeholders and to try and iron out some of these controversial issues and then come back at a later date with either revised or new issues after you have met with the various groups. We met on September 13, 2000, with industry; the medical and scientific community and went over quite a few of these issues. I think we resolved quite a few of them at that time.

We planned for additional meetings. We were going to meet to discuss lamp compatibility.

That's if your lamp burns out and you need to replace it, what qualifies as a replacement lamp. We were originally going to do this in September, but that meeting got postponed until February 7th and 8th of this year. So it's a relatively recent meeting.

Item number two there. We did meet with Health Canada in September. We had to postpone the meeting because of the events of September 11th, but the people from Canada had already purchased their tickets and said can we come down and talk to you anyway. It would be beneficial for both of us to talk about mutual standards between the two countries. So they did come down, and we spent a good day talking with Health Canada in September of last year.

With regards to education, you asked us to strengthen our educational efforts. We have started some collaboration with the Conference of Radiation Control Program Directors. They have suggested state regulations on how states should regulate sunlamps in their particular jurisdictions. We had a meeting with them.

We also discussed educational efforts at that particular meeting. I would note that the

industry itself since our deliberations a couple of years ago have started quite a few programs on their own in terms of education. There seems to be quite an effort on the part of the industry in this particular area.

Also in the meantime, CDRH, our group is convinced that more research was necessary particularly on the issue of recommended exposure schedules. We want to know how different people with different skin types tan and how long do they maintain that tan. I want to talk to you about two studies.

We have one which is more than halfway done, almost towards completion. That is to look at the various measurement techniques, instruments, biopsies, and studying thymidine dimers and things like that to try to get a better feel for skin sensitivity to UV. We've had more than 100 human subjects in this study. I think about 70 have partaken right now. We're trying to finish the study off.

The second part of this is a new study. That is to actually do the job. That is to come up with a recommended exposure schedule for producing and maintaining tans. This will be using

lamps that are more similar to those that are used in the salon. For purposes of science in the first part and to get the job done quickly, we use lamps which have more UVB then is currently used in salons and are not typical of those used in the salon.

Today we're back here and we think we're ready to go forward with four proposed revisions. These are revised warning labels, the inclusion of these labels or statements into catalogues, specification sheets and descriptive brochures. We also want to visit the question of who is a manufacturer. That is someone who makes significant modifications that affects the performance as specified in the standard. There are certain performance requirements spelled out per se in the performance standards. If you do something that dramatically changes those requirements, you assume the responsibilities of becoming a manufacturer.

This requirement is already per se in the device laws. It's incorporated in the laser standard. We wanted to put it per se into the performance standard for sunlamps. The last of the four is revised specifications for protective

eyewear.

Rationale for these revised proposals. We wanted a clearer, user-friendly warning label. What we have now is a rather long paragraph. We wanted something that is easily read. We wanted the warnings to appear in home-use products and in advertisements. The part about advertisements is new. The appearance in home-use products, there are labels on the products, but the customer who buys it doesn't actually see the label until such time as they have purchased the product. So that's one of the rationales for including it in the advertisement. You can see the warning labels before you've actually made a purchase.

CHAIRMAN ROTHENBERG: Could you just put it back on the slide show mode so it'll be bigger for the audience?

DR. CYR: Requirements for a manufacturer is something that we wanted to include in the performance standard per se. I've already covered that. It's part of medical device regulations, and it's in the laser standard. We wanted to put it into the sunlamp performance standard.

We also wanted to incorporate new

requirements for protective eyewears that are more quantitated and consistent. You notice I put the word goggles in parenthesis here. This is because the international community prefers that word. That's a word that they like.

We use the word eyewear. I think of goggles as most Americans do as something big and bulky whereas eyewear can be rather simple that just covers the eyeball. If we were to go toward an international standard, the decision between eyewear and goggles would have to be ironed out. Maybe we would leave it this way, eyewear (goggles).

Here's the existing warning statement. Danger, ultraviolet radiation. Follow instructions. Avoid overexposure. As with natural sunlight, overexposure can cause eye and skin injury and allergic reactions. Repeated exposure may cause premature aging of the skin and skin cancer. This goes on for three slides.

Wear protective eyewear. Failure to may result in severe burns or long-term injury to the eyes. Medications or cosmetics may increase your sensitivity to the ultraviolet radiation. Consult physician before using sunlamp if you are

using medications or if you have a history of skin problems or believe yourself especially sensitive to sunlight. If you do not tan in the sun, you are unlikely to tan from use of this product. Having gone through three slides and read that you can understand maybe why we would want something in bullet form and a little easier to read and understand.

This is what the international community has come up with. Warning. Ultraviolet radiation may cause injury to the eyes and skin such as skin aging and eventually skin cancer. Read instructions carefully. Wear protective goggles provided. Certain medications and cosmetics may increase sensitivity.

I put this up here because we presented this earlier at one of our meetings and there was considerable concern about the word "eventually" and that's why I have it in italics. That almost implies that it's inevitable. That's certainly not the case. Not everybody who goes to the beach or who goes to a tanning salon will get skin cancer. So we certainly took that under consideration and have dropped that word from what we're proposing on the next slide.

The other change that we'll make between this slide and the next one is the very last line. Certain medications and cosmetics may increase sensitivity. People told us that they wanted the words sensitivity to UV radiation. I did make that change.

Here is the revised warning statement that we are suggesting today. Warning. Ultraviolet radiation may cause injury to the eyes and skin. Skin aging, skin cancer. Read instructions carefully. Wear protective eyewear (goggles) provided. Certain medications and cosmetics may increase sensitivity to ultraviolet radiation.

We also propose that these warning statements be included in all catalogs, specification sheets and descriptive brochures and any other purchasing information pertaining to each Sunlamp Product and ultraviolet lamp. A legible reproduction of the warning statement required by the Code of Federal Regulations Chapter 21 and Part 1040.20. That's the performance standard.

It also says that the modification of a Sunlamp Product previously certified under this chapter by any person engaged in the business of

manufacturing, assembling, or modifying Sunlamp Products shall be construed as manufacturing under the act if the modification affects any aspect of the product's performance or intended functions for which this section has an applicable requirement. The manufacturer who performs such modifications shall re-certify and re-identify the product in accordance with Chapter 21 of the Code of Federal Regulations.

Examples of some of the modifications are if you change the warning labels on your product, if you go beyond the maximum exposure timer limit that's part of the standard. They're spelled out into the performance standard. You can easily see what those are.

I know that the industry has some major concerns about this. Some of the speakers will be addressing that. They'll want more detail than that. I sympathize with them on the detail. I think it's something we can work on. I'm not objecting at all to what they're going to present since I've seen it. It looks reasonable that we negotiate with them to try to iron out the details.

Protective eyewear. I want to tell you what's there right now. Currently it says the

spectral transmittance shall not exceed a value of 0.001 over the wavelength region 200 to 320 nanometers, that's a UVB region, and a value of 0.01 for a 320 to 400 nanometers, the UVA region, and shall be sufficient over the wavelength region above 400 nanometers, the visible, to enable user to see clearly enough to reset the timer.

We're going to make some changes regarding some levels and wavelengths. We also certainly want to change the last one because nobody right now goes and resets the timer. That's not done. We don't want people to do that. You should be able to see the stop button to shut the emissions off, but once you set it, that's it. It's usually done out at the desk, not inside of the room. That's my understanding.

Here's the proposal. This one is wrong. Obviously since I messed up my slides, I have the wrong one here. For a visible region, a more quantitative definition, the luminous transmittance shall not be less than one percent and the unweighted transmittance between 400 and 550 shall not exceed five percent. The measurements are over a five nanometer interval, not a two. These are last minute changes that we

messed up on. So it's a five nanometer interval and the wavelength region applies to the unweighted transmission.

Some other issues that we've been discussing. I told you that we had a meeting on February 7th and 8th about replacement lamps. We want to determine an absolute method of compatibility. We think we should be ready for a presentation of this issue at the next TEPRSSC meeting. It's going to take us that long to prepare a proposed rule. There are lots of steps in the writing of a proposed rule. We'll be doing that in the next year but also preparing this extra issue to present next year, and only then would we go forward with a proposed rule.

We have been discussing other issues which we think are more long-term. That's being brought about because of our interest in coming up with international standards that are harmonized between the various countries. Again this goes back to some of the things which were controversial; the non-melanoma skin cancer action spectrum which is used in the classification of lamps into categories and also some caps on irradiance, how strong a delivery of dose can be

given from these particular products. I'm not going to say much more about these. These are still from our concern from the Center as being in development and being discussed.

In summary, I've presented four proposed amendments at today's meeting of TEPRSSC. We think we'll be ready with a fifth one at the next meeting involving a lamp rating system. We will obviously continue on with our evaluation and laboratory studies that are ongoing. We will work toward international harmonization efforts that are coming down the road. Thank you.

CHAIRMAN ROTHENBERG: Okay. Thank you. Are there questions from the Committee?

DR. LAMBETH: I have a very brief question on your eyewear (goggles) proposed statement. Why did you limit it to 550 nanometers, the transmittance? Should not be less than one percent over the 400 to 550. I assume this is the region where you're trying to make sure the person can see.

DR. CYR: Right. I'd like to introduce Sharon Miller our engineer from the Office of Science and Technology who is the expert on the eyewear part.

MS. MILLER: So you're wondering why we're limiting the transmittance over the 400 to 550 nanometers?

DR. LAMBETH: No. You've made sure people can see. You have at least one percent transmittance over the blue and up to the green. But what was the one with the red?

MS. MILLER: Okay. No, that was the error in the slide. The one percent lower limit on luminous transmittance by definition that actually covers up to 780 nanometers.

DR. LAMBETH: Okay.

MS. MILLER: But the 400 to 550 is for the five percent cap just on unweighted transmittance. We need to correct that in the handout. That's to protect the eye from too much visible light.

DR. LAMBETH: I was looking at the handout. So the slide was different. Is that what you're saying?

MS. MILLER: No, the slide was the same. It was also an error. Both the handout and the slide were done before we --

DR. LAMBETH: Okay. So you're limiting it to five percent total transmittance in the --

MS. MILLER: 400 to 550.

DR. LAMBETH: That's an integrated transmittance.

MS. MILLER: No, the transmittance would be measured at five nanometer intervals, and we don't want that value to go above five percent anywhere in that wavelength region.

DR. LAMBETH: Okay. Then above that wavelength?

MS. MILLER: Above that wavelength region it could as high as they want because that's not a hazardous region for the retina.

DR. LAMBETH: Okay. So the 550 is hazardous?

MS. MILLER: Well, we know that the blue light hazard function starts dropping off between 500 and 600. The reason we chose 550 was because that's the wavelength region that's been in the IEC standard for several years. I can't say that 550 is a cut-off point between hazardous and not hazardous. That's just a practical region to use.

DR. LAMBETH: Okay. Thank you.

CHAIRMAN ROTHENBERG: John.

DR. SANDRIK: Yes. Just to pursue that

a little further. I guess I sympathize with your intent to have a more quantitative standard there. As Dr. Cyr indicated, the purpose has changed from resetting the timer to just shutting off a button or something. But I guess there's the value in the indication of why it is you want to have a certain level of transmittance and I guess it's to be able to see something.

I guess at these levels it would probably assume that this shut off button is illuminated at some particular level of luminance so that when it comes through this eye-goggle you can see the shut off buttons. Is there some sort of typical standard level that this thing is illuminated at or it's self-luminous or something, so that you can always assure that you can see this thing at this level of transmittance?

MS. MILLER: No. Currently I don't believe they are luminated in general, and there's no requirement for them to by illuminated. But the one percent luminous transmittance we've worked out with other engineers on the IEC Committee, just based on qualitative tests of eyewear, holding them up in sunbeds and saying can we see what we need to see and then measuring the luminous transmittance,

that value seemed to be a reasonable value to allow people to see well enough to push the stop button or get out of the bed if they need to and just see well enough to be able to function.

DR. SANDRIK: Okay. So essentially the stop button is probably being illuminated by the --

MS. MILLER: By the light from the bed.

DR. SANDRIK: From the bed. You can probably assume that there's some level of luminance or illuminance that gives you enough to see by. Okay. Thank you.

MS. MILLER: Right.

DR. LAMBETH: I'm still a little confused. Could you just read me the proposed proposal? What we have isn't right.

MS. MILLER: Okay. Right. I don't have it in front of me. The requirement is that the luminous transmittance which is a calculated value based on the spectral response of the eye, that is a function that goes from 380 to 780 nanometers. So you'd have to calculate the transmittance of the eyewear, multiply it by that function, in addition multiply that by a standard light source spectrum, integrate that, and then divide that by --

It's a complicated formula. So that's a value that's based on the integrated transmittance of the eyewear over the 380 to 780 nanometer region. That should not go below one percent. Really this is a quantitative way that you can measure that will meet the same requirement that we have now that says you should be able to see clearly enough through the eyewear to be able to reset something or push a stop button.

Then the other requirement is a cap on how much transmittance you can have in the visible region. That is that the spectral transmittance of the eyewear between 400 and 550 nanometers measured at five nanometer intervals shall not go above five percent.

DR. LAMBETH: Okay. Thank you.

CHAIRMAN ROTHENBERG: What are the UV numbers?

MS. MILLER: We haven't discussed UV limits because those are going to remain exactly the same as they have been.

CHAIRMAN ROTHENBERG: Just for reference, what are they?

MS. MILLER: That's 0.1 percent in the UVB and one percent in the UVA.

DR. BENSON: Is the revised warning statement also going to be on the boxes of sunlamps purchased for home use as well? Would it be the same statement or a different statement?

DR. CYR: Our intention was that it would be the same statement.

DR. BENSON: Okay. Because it says "wear protective eyewear (goggles) provided." Are they going to be in the same box or is it encumbant upon the purchaser to buy their own eyewear?

DR. CYR: I know that some people from the industry are going to address that issue. There's a debate as to what that means in the standard as being provided. The custom right now is that most customers going to the salon purchase their eyewear. If the customers apparently don't want to do that for some reason, they will be provided with eyewear as required in the standard. But the custom and tradition is that people buy their protective eyewears. There's a wide range of different colors and sizes and shapes. That gives them a choice as to what kind they want.

DR. BENSON: But there's nowhere in here about that. For someone buying a sunlamp to use at home, there's nothing to indicate that there

is a certain kind of approved eyewear that they need to look out for.

DR. CYR: Good point.

DR. BENSON: And that it's not simply sunglasses.

DR. CYR: Thank you. I had not thought of that. The change on eyewear came to me last evening. I will incorporate it into the slides and mail the new slides to you by E-mail to all those who sign up on the sheet here. So be sure to sign up on the sheet and I'll get copies of the new slides to you.

AUDIENCE MEMBER: All units come with eyewear.

DR. CYR: All home units come with eyewear.

DR. BENSON: And this eyewear would conform to these standards.

DR. CYR: They would conform to the standards, right.

DR. BENSON: Okay. And there's something on the box that says wear the eyewear that is given to you and none other.

DR. CYR: Yes.

DR. BENSON: Okay.

DR. CASWELL: A couple of brief questions. First, in your warning statement, why skin aging rather than a more generic photo aging? Any reason for that? Is it to conform with IEC?

DR. CYR: That came out of IEC I suspect because photo aging may be a term that many clients wouldn't understand. It's a good scientific term. I understand it and you do and others, but it may well be that they thought an average person might not understand the term photo aging.

DR. CASWELL: Okay. The second question, Dr. Cyr, is in terms of the manufacturing issue, who is defined as a manufacturer? It's my understanding that tanning beds are Class I medical devices.

DR. CYR: Right.

DR. CASWELL: Do manufacturers of Class I medical devices need to be licensed?

DR. CYR: No.

DR. CASWELL: No. They're exempt from that. So that would not be a requirement for someone who wanted to modify a tanning bed.

DR. CYR: I'm not following the question.

DR. CASWELL: If a salon operator wanted to retro-fit a tanning bed to modify the specifications, the performance characteristics of that tanning bed, they could do so as long as it met the current performance specifications.

DR. CYR: Right.

DR. CASWELL: Okay. Thank you.

DR. CYR: The discussion was can you change an acrylic shield or something like that.

DR. CASWELL: Right.

DR. CYR: You can put in lamps that are compatible. We have a policy letter on compatibility. You can make those kinds of changes.

CHAIRMAN ROTHENBERG: Yes.

DR. MABUCHI: Just one minor question. In the warning, you say injury to the eyes and the skin. The skin aging and skin cancer. Are you implying there is some other type of injuries to the skin other than skin cancer and aging?

DR. CYR: Other kinds?

DR. MABUCHI: You're saying injuries to the eyes and skin and also the skin aging and skin cancer. Does it imply that there are other skin lesions besides skin cancer and aging?

DR. CYR: There are talk about immune effects but we didn't include anything like that in there. Oh, burns, yes. Sunburns, sure.

DR. CASWELL: But those are acute effects.

DR. MABUCHI: Acute effects, yes.

DR. CASWELL: These are really addressing chronic effects.

DR. CYR: We meant to include acute effects in there too. That's what is meant by injury to the eye and skin were burns.

DR. CASWELL: That covers it.

DR. CYR: I know that one of the comments will be to put sunburn per se into that warning statement.

CHAIRMAN ROTHENBERG: Yes. I think what I'd like to do is have some public comments and we're still going to continue discussion after that. So why don't we go ahead with the speakers? The first speaker will be Don Smith. Would you please just identify your organization, *et cetera*?

MR. SMITH: Can you hear me? Is this on? Two years ago when I left this meeting and was flying back to Tucson, Arizona I realized that we were going to need scientific information to

present to this Committee on a number of subjects on down the line.

CHAIRMAN ROTHENBERG: Can you just identify --

MR. SMITH: So we formed the UVR Research Institute which is a division of the North American Alliance of Tanning Salon Owners. The UVR Research Institute occupies 1,950 square feet. We have sophisticated spectroradiometric and other testing gear. We have set out to try to identify those things we need to know about the testing of sunlamps, sunbeds, eyewear, *et cetera*. So that's been our basic purpose.

I would like to mention that Dr. Cyr has been very good about removing a lot of the offensive words. We could argue about the warning label forever. But the only comments that I would like to make are from our side of the point we are concerned about when we get this global harmonization that comes to us.

(1) The culture is different. The language is different. So we have problems with that. (2) In the European system as best we can identify it there is no opportunity to have sessions like this where you can make comments.

Some of the things that come over to us we're a little concerned about what we're getting that anybody's had any input on.

Regarding the warning label, the only changes I still was arguing with Dr. Cyr last week is I believe that instead of saying "may cause" that it's more scientifically correct to say "may contribute to these things." I'd asked him to put sunburning in there because that's the most leading cause.

Let me just tell you that my remarks are made from the point of view of all of us that are out there actually tanning the people in the field. No one will ever look at these warning labels on the beds. That just doesn't happen. They're in there to get their clothes off and get ready.

So it may be helpful for you to know that there is a form that is generally in use that's a client release and informed consent form that will be changed to conform with whatever language. It goes into much more detail that the client signs and fills out at the time that they do it. So that the label that's on the bed is just a small part of what we're doing to properly inform

the client as to the risks involved in the tanning procedure.

That may help you to see that we do this. This is accompanied with just for your information a complete skin typing, sub-typing form so that you can't set up exposure schedules as you know unless you know the skin type, sub-type of the individual. These are on the front and back and the client signs those things and they're kept for permanent record. That's all the comments I had to make on the warning label, just to thank Dr. Cyr for being so kind to address all these.

I'd like next to discuss the issue of the definition of a manufacturer because that's the one that causes the most concern. We had a meeting on the 7th. We submitted that on the testing of a single lamp and a test stand are standard procedure. We went a long way. I'd recommend that we meet again in September or October and again next year in February because I believe we have the capability of coming to this Committee next year and recommending a standard protocol for both the testing of a single lamp and a test stand and which is more complicated testing the array, *i.e.*, the complete sunbed.

My concern with this is we talk about any aspect of the products performance or intended function. We know what the intended function is. That's not a problem. If we do not have a standard protocol for testing the array, *i.e.*, the sunbed, how are we going to determine performance? We can't. That's the problem that we have with it, not that there isn't a valid reason on this.

I've asked the question and the material you have is how can FDA recommend that TEPRSSC approve this if it's based on the standardized measurement at performance and yet we have no standard protocol for measuring performance. So it seems like we got the cart before the horse.

Therefore, our recommendations to this Committee is to reject this approval of Amendment 3 once again and challenge us all to meet again this fall and meet again next spring and come to you with two documents. One is a standard protocol for testing a single lamp and a test stand which will resolve the lamp compatibility issue. Two is a standard testing protocol for the array, *i.e.*, the sunbed so that we can resolve all the other issues that stem from that which is exposure schedules, *et*

cetera.

Now we're ready to present this in September. We've come up with a new spectroradiometric technique where we can measure the change over time. We read the entire spectrum. We can follow it. So there's performance degradation in both the lamps and the bed. We've also developed a new eight-point technique to where we measure the radiation around the whole body. What those two things allow us to do is to calculate the dose delivered during that session. We think these are interesting to note.

So I believe that we can't do this now unless and until we do these things. If we do it now, it's going to be left up to the manufacturers to decide. They're going to say you have to buy our parts. It's going to put the tanning salon owner at a distinct disadvantage. Let me tell you how important these are.

If a salon owner is considered to be the manufacturer or record on a product, the manufacturer's warranty and product liability insurance will be null and void. That avenue of coverage for the public is gone. I've checked with all five of the insurers who insure tanning salons.

They assure me if a salon owner is named the manufacturer of record, that coverage is gone.

So what we do here if we're not careful is we now have the public dealing with a situation that has no insurance coverage. That's how important it is. My recommendation is let's define performance first. Let's come back to you next year and do that.

The next area is to get into the issue of eyewear. We have tested all of the leading eyewear that are sold. Based on the old 0.1 and one percent standards, we believe that all of it is in compliance. We'll get differences between lenses. We do not believe that the products sold including the disposables that we're providing to the customers present any risk to the industry.

I'd like to bring you to Dr. David Sliney of the Army that a lot of you know is the expert in it. He says in a 2001 paper that we don't really know how much is safe and we don't have any answers to these questions.

I'd also like to point out to you that in doing this research to talk to you about this I began to look at it in light boxes where we set 13 inches away for 20 minutes have 10,000 lux. If you

can't handle that, you can go 5,000 lux for 60 minutes. We decided to measure in a standard sunlamp that has a 20 minute time to 4.0 MED. We measured 1,743 lux.

So we're dealing with a different phenomenon here that we have to keep in mind. I then took this and said if this was this five percent T thing if we applied that to the box, you can see what that would mean. Going beyond that, we said there's a lot of evidence and then there's the citations, studies done for the military and they found that it took 23 percent transmission in the visible range in order to have the proper visual acuity to see the cockpit dials.

Let me tell you the problem we're facing from my side. Right now the new beds that are coming out have all the controls all around the canopy. There's fan controls, aromatherapy controls, up and down controls. So what happens today with the old generation of eyewear that restricted to this under five percent is those people must take off those goggles to see the controls. That isn't productive. All of us agree that it shouldn't happen.

The new generation of eyewear that's

come out allow enough additional vision to where they can see these controls with them. Now while some of those products out here today would be grandfathered if we're not careful about this five percent, we'll create a situation where we're going to mandate that these people have to keep taking their eyeglasses off to see them.

Just one more slide to show you this is some work that we've done where we've compared sunlight with an Optronic 754 spectroradiometer. The sunlight data was determined on August 28th at 11:30 p.m. As you know if you're going to talk about sunlight and make comparisons, you have to precisely define the terms under which you measured that sunlight.

As you can see here, we have sunlight. If we're worried about the retinal burns from the visible range, we have a lot of problem in the sunlight. Yet the military specs are 25 to 50 percent for visible light transmission for sunglasses. So that's the problem that we have if you begin to look at these things. Plus there's some concern as Sharon Miller raised about is there a problem with high pressure lamps.

Remember the typical sunlamp is a three

to four percent UVB which is why Dr. Sliney is concerned. That's the most dangerous ranges we're working with for the eye. High pressure is about 0.4 percent. We're dealing with a different issue.

Here's the recommendations. You have a copy with you that we have made. We'd like to present for your proposal. I'm not sure Sharon if I have those numbers right, but it's now as I understand it 380 to 780 which is what we thought it was Monday. Then down here it is now 400 to 550.

We're trying to solve the problem of having enough light to see these off switches and the controls. That's what we want to do. If we're not careful in the older products, it forces them to remove it. The new generation of eyewear allows more visible through. But they typically will range in the ones that we've tested in the 15 to 35 percent range. That's still within the 25 to 35 percent range of sunglasses for military aviators. Clearly the existing products would be grandfathered, but it would prohibit the development of new eyewear that people can see these controls. If you've ever had a chance to

look at these beds, they have stuff all over them that you have to see.

So what measurement device will we use? Are we going to use a spectrophotometer with a Tungsten bulb? We believe that we should use both tube-type and high pressure lamps because that's what we're in the cabin. That's what we're using. So our testing has been done on real, live tanning lamps.

Today out of the Institute they're testing high pressure lamps with the various eyewear. We set up a field. We know the irradiants. We put the eyewear device in the middle. We read it just like the eye would see it. We have some concern about this.

If you want to look at light boxes, the light boxes I mentioned to you have 10,000 lux that you set 13 inches away. If we have a problem here, FDA ought to jump on these light boxes really quick because we have 1,700 lux and they have 10,000. We need to put these things into perspective.

What we would recommend is that we need to decide what we're going to do; spectrophotometer, spectroradiometer. Our thoughts as of a meeting we had Monday is we probably ought

to do both. We're testing today also a high UVB percentage. We have lamps that approach eight percent UVB. That's probably the worst case, and we think we ought to test it there.

You need the filters. What device and the distance of the eyewear? So we need to set up parameters on how we're all going to test these eyewear. Then set up an ad hoc committee is what I recommend. There's six companies that make eyewear. There are some of us that are interested. Dr. David Sliney would be an excellent additions and there are some experts at the FDA.

Let's study this. Let's find out what more than percentage makes good. Is five percent right just because somebody from Europe put this in something that we can't find the documentation on? What we recommend is this Committee consider giving conditional approval but write the five percent in with a pencil until we can study this. It shouldn't take us but a month or two to do so. I also recommend as I mentioned a meeting in September or October and one again next February or March so that next year we can come in and present a lot more information to you. Thank you.

CHAIRMAN ROTHENBERG: Thank you. Could

you just tell us how many people are involved in the Institute, the staff?

MR. SMITH: Well, we have three of us that are in there most of the time. Barbara Grant is in there full time running the spectroradiometer. She has a Master's Degree from the University of Arizona. We're poorly funded and small, but I think as Sharon Miller and the people can tell you we've presented I think some pretty valuable information. We've gone in and tried to look at the basic things of how the sunlamps and sunbeds work.

CHAIRMAN ROTHENBERG: Okay. Thank you. We must move on to our next presenter who is Joe Schuster.

MR. SCHUSTER: Good morning, ladies and gentlemen, TEPRSSC Committee. My name is Joe Schuster. I'm the Vice President of tanning products for the sunlamp manufacturer Light Sources, Incorporated. Today I'm speaking on behalf of the Indoor Tanning Association. My comment will mainly focus on the labelling issue that you see in front of us.

As Dr. Cyr pointed out in previous meetings we've not had significant changes to the

standard since 1986. With that in mind, we'd like to make sure that the labelling is very clear to the end user so that there's not an undo public health risk. With the way it's set up right now if you take a look at it, we think that it may be confusing that regardless whether or not you wear eye protection, you still may have eye damage. What we'd like to see is with the first bullet point. Ultraviolet radiation may cause injury to the skin. Skin aging, skin cancer. Read instructions carefully.

When it comes down to protective eyewear, you'll see and I think one of you noted earlier there's really no definition as to what type of eye protection is necessary. The way it's looked at now, you could wear sunglasses if that's the case. We think it should be clearer defined.

With that in mind, we feel that this bullet point should read wear federally compliant eyewear. Unprotected exposure to UV radiation may cause eye injury. We feel that's a little bit clearer in the definition. That certainly will keep people away from an undo health risk. Any questions?

CHAIRMAN ROTHENBERG: Any questions?

(No response.)

CHAIRMAN ROTHENBERG: We will have a more extended discussion session.

MR. SCHUSTER: Thank you for your time.

CHAIRMAN ROTHENBERG: Thank you. We'll move onto the next speaker who is Steve Mackin.

MR. MACKIN: Good afternoon. I'm Steve Mackin. I'm from Solartech Incorporated. We're one of the several companies that make handheld UV meters to measure either outdoor UV index which the EPA is using some right now for the Sunwise School Program. We also make meters for measuring indoor ultraviolet, total UV, UVB, and MED per hour.

This is hard to read but it's a one pager trying to emphasize the importance of eventually standardizing on outdoor versus indoor MED definition. The FDA has proposed to define type II skin MED as 200 Joules per meter squared effective Diffey for sunlamps. That actually brings it very close to the 200 Joules per meter squared that the WMO and the EPA is currently using for the UV index. We support that, and we think it's a very good idea. As you know, today it's 156 Joules per meter squared.

If that does come true, this has some

bearing to the definition of a manufacturer amendment that you've just been considering in the sense that it will give everybody a uniform way to determine the effectiveness of the sunbed and relate it to the outdoor index as well. They'll be basically one and the same since the erythemal irradiance is the same for both.

Accordingly if NWS and WMO decided to adopt 200, they could actually change the UV index by taking a dividing factor from 25 that it is now, the WMO, down to 24. They'd have something totally compatible. Or if the FDA decided they wanted to go to 210, then it would be identical to the UV index.

At the previous meeting in February, Don Smith presented some information about possibly using 180 Joules per meter squared. That would give one MED and one SED, one SED being one-half of one MED, it would give it an exact relationship to one UV index. So that's another thing that could be considered.

It's our opinion that having different MED definitions and EAS weightings between sun and tanning lamp measurements leads to confusion and lack of common understanding. Since modern

sunlamps are very close to what we call the standard sun spectral irradiance, there doesn't seem to be any reason why we should keep them separate anymore. They should be identical.

Just a note here. The standard sun is 9.3 on the UV index or four MED per hour which just happens to be the same as a tanning bed max timer schedule of T_e. That's at 210 Joules per meter squared. Using 200 as an MED, the standard sun would be 8.9. If you round that off to nine, you can see that a tanning bed reading 27 on a UV index would be three times stronger than a standard sun. Hence the 20 minute T_e or maximum timer to form that would be understandable.

The last half of this has to do with potentially in the future considering the non-melanoma skin cancer action spectrum as part of the equation for measuring sunlamps. Our position is that would confuse things even further because it's very similar to the Diffey curve but it starts out lower at 280 and it rises up toward 297 then it pretty much follows the Diffey erythemal curve beyond that. It has two specific wavelengths that it cuts off at for UVB and UVA and would be difficult to measure.

That's about it. Basically asking that we consider sunlight and tanning lamps as similar as far as erythemal effectiveness goes and taking them together. There's one more slide here.

DR. LIPOTI: Larry, while he's putting up the other slide could you ask Steve Mackin to please define NWS, WMO, MED?

MR. MACKIN: Sure. National Weather Service, World Meteorological Organization. What was the other one?

DR. LIPOTI: MED.

MR. MACKIN: Minimal Erythemal Dose.

CHAIRMAN ROTHENBERG: And EAS.

MR. MACKIN: Erythemal Action Spectrum.

CHAIRMAN ROTHENBERG: Anything else?

MR. MACKIN: Sorry. I'm so used to those abbreviations.

CHAIRMAN ROTHENBERG: Yes. Most of us are not necessarily familiar with those.

MR. MACKIN: It's a Word Document.

CHAIRMAN ROTHENBERG: It's a Word? Okay. We're in Power Point and we want to be in Word.

MR. MACKIN: All files.

CHAIRMAN ROTHENBERG: Any other brief

questions?

MR. MACKIN: Well, rather than show that slide, in your handout there's a graph basically that shows the Diffey erythemal action spectrum which is the black line. It is basically weighted at one all through the UVB range up until about 297. Then it heads down to about 330. Then it goes out at a lesser slope towards 400. The idea of measuring either UV index or MED per hour is to try and replicate as exactly as you can that particular weighting function. This particular meter follows the blue line there.

The other action spectrums that people have considered, I believe there's an FDA specific one and there is the potential and non-melanoma skin cancer one, the slope are almost identical. The reason I brought it up in the one pager there is that if we settle on one action spectrum for outdoor sun which is that one for the UV index and the National Weather Service, let's at least stick with that for indoor lamps. I believe that's pretty much the way they're heading. That's it.

CHAIRMAN ROTHENBERG: Thank you. We have one more speaker, Bob Levin.

DR. LEVIN: I'm Bob Levin. I'm with

Osram Sylvania. I'm here to discuss one particular aspect of tanning lamps. That is a problem of lamp compatibility that may compromise exposure safety.

There are new regulations under consideration now which may resolve this. They come in the future development as opposed to the immediate proposals. Lamps are identified in terms of two functions now. One is in erythemal weighting. Another is melanogenic weighting. They're very highly correlated. So in my discussion, I will just use the term erythemal at the moment. There's no reason to make a distinction.

The method of identifying lamps at the moment is to take a spectral power distribution at a fixed specified point with respect to the lamp and from this calculate the time for a prescribed erythemal dose. This is refered to as T_e, the permitted exposure time. Note this a benchmark value for a lamp that has nothing to do with actual exposure in a tanning system. It's a historical artifact because in an actual tanning system there are multiple lamps and the system will also affect the exposure.

However, the systems are certified for

a particular manufacturer's lamp type. It is important that other manufacturer's lamps be substituted, for example, matter of availability at times. The existing rule for the compatibility of lamps is that the T_es for the original lamp used to certify the bed and for the equivalent lamp that is substituted may not differ by more than ten percent.

However, at the present T_e is not an absolute value. It's not possible to determine a value unique to a lamp because it depends upon the test factors, how hard the lamp is driven, and even such things as ambient temperature can have significant effects. So one cannot look at the original manufacturer's published value T_e in the FDA submittal and use that to make an equivalent lamp.

However, it is very possible to compare two lamps because the effect of the ballast, the effect of air temperature, and the other testing conditions generally produce second-order changes in the lamp. Both lamps would be affected by the same amount if you tested one of the original lamps and one of the supposedly compatible lamps. If you examine the ratio of the T_es calculated by this

method, you can determine whether or not lamps are compatible.

Our manufacturing group has been benchmarking lamps in the industry. Then we have had comments and test data from our various customers suggesting that lamps that are incompatible are often being substituted today. We brought some lamps into our standardizing laboratory that confirmed this. We decided to run an independent test to illustrate what this effect is.

We picked one of our popular lamp types for this test. We identified four other lamps that were claimed to be equivalent. We obtained samples of all lamps that were new but had already been distributed to the industry including ours. These were randomly chosen. We located two production codes for four of the five groups, meaning we were not going to have biased results due to an outlier manufacturing group.

We randomly selected lamps from the various cases of lamps we obtained and sent them to an independent testing laboratory. They were tested in a consistent manner. The manner we used were the ANSI specifications for safety testing of

lamps. Would you please put the overhead on? I will show you the results. This is also in your handout. Thank you.

The average T_e value of the original reference lamps was 74 minutes. Those are the two groups at the left of the screen. We used three lamps in each group for our initial survey, and the differences were significant enough that we did not extend statistically. The T_e ratios of the other lamps to the standard lamps ranged from 0.5 to 0.63, far from compatibility which would require somewhere between 0.9 and 1.1.

It was also interesting in all cases of non-compatibility that we found in these in other lamps. The differences were in a direction to increased exposure and increased potential risk of both acute and chronic effects. Tanning systems have schedules based upon the certified lamp, the original lamp for which the bed or chamber was tested. Since reciprocity holds here, you can change equivalent time to exposure. You have 60 to 100 percent higher irradiance exposure than intended with non-complying lamps from this test.

Consequently the clients can be subjected to as much as twice the intended

exposure. This constitutes unnecessary exposure. Our concern is that there are adverse chronic effects of tanning that correlate with cumulative exposure dose. This increase for a single exposure may cause minor acute effects but the cumulative exposure could cause significant chronic effects.

We feel that this is a problem that can be addressed now. It does not have to wait for additional regulations. We believe that the FDA should look into this and remove non-compatible lamps from the market. Thank you.

CHAIRMAN ROTHENBERG: Okay. We've heard a lot of things from a number of different people. What questions or comments do we have from the Committee?

DR. CASWELL: I have a question for both for Bob and Don Smith. If a lamp is incompatible now, who's responsible for that incompatibility? Is the manufacturer responsible for that or is the tanning salon owner for that under current guidelines?

DR. LEVIN: It's the responsibility of the manufacturer of the -- compatible lamp because they publish in the literature and package inserts that the lamps are compatible. The tanning parlors

rely upon this as proof of equivalence.

DR. CASWELL: Bob, could I follow up on that just a second? So you have documentation on the compatibility of these lamps that you tested.

DR. LEVIN: Yes.

DR. CASWELL: It's not just verbiage.

DR. LEVIN: No, we have reports from independent labs in addition to our own. These reports have been turned over already to the CDRH.

DR. CASWELL: Thank you.

MR. SMITH: The answer to your question is and checking with the five leading insurance companies, it's the salon owner's responsibility. That doesn't mean other people wouldn't be sued, but we're ultimately responsible. If a state regulator is going to close down a salon, they don't hold the manufacturer or distributor responsible. They hold the salon owner responsible.

DR. CASWELL: Dr. Cyr, under your proposal for establishing an individual who modifies a tanning bed as being responsible being the new manufacturer, do you see that much would change in terms of the way the operation is now? Are we just codifying what in fact exists right

now? I guess that's my question.

DR. CYR: My understanding is that we're codifying what already exists. We're not making any dramatic changes to the present day requirements.

DR. CASWELL: Thank you.

MS. FAHY-ELWOOD: I just had a follow up question about the eyewear issue. I was wondering what your position is on the adequacy of that visible light transmittance cap for people in the bed being able to see what's going on.

DR. CYR: The issue of the five percent being the tops?

MS. FAHY-ELWOOD: Yes.

DR. CYR: Sharon, do you want to address that?

MS. MILLER: So you're wondering if five percent is possibly not adequate?

MS. FAHY-ELWOOD: Is inadequate, right.

MS. MILLER: The five percent value was basically chosen based on an analysis for possible retinal damage from a situation that we would consider worst case which is a sunbed that has what's called a high-pressure lamp. The arc of the lamp is very small. When you have a lot of

radiation and a small area on the retina, that's a more hazardous situation than a case of typical tanning beds when you have many fluorescent lamps and it's a large field.

In fact, when Don presented the data of the SAD units that are used for depression, he's right. Those are much brighter. They probably aren't posing a retinal hazard. What we were trying to accomplish by putting the five percent cap was to cover the worst case scenario of a bed that has either a facial high pressure lamp or some beds have nothing but high pressure lamps.

MS. FAHY-ELWOOD: And what about the one percent? Is that adequate for people to actually see what's going on in the bed?

MS. MILLER: Well, we think it's kind of based on --

MS. FAHY-ELWOOD: Or should it be less than one percent?

MS. MILLER: No, it should not be less. That's the floor, so it should be above one percent.

MS. FAHY-ELWOOD: Okay. I see.

MS. MILLER: If it's right at one percent, some things may not be able to be seen.

This phenomenom of putting many controls and displays in the bed is fairly new. We have test data probably from the year 2000 and back that shows that the five percent cap would not eliminate any eyewear from the market. Now there are newer beds with more controls inside and newer eyewear that's more transmissive that would not meet this requirement.

I've spoken to the person that we consult with who's an expert on eye safety, Dr. David Sliney, that Don Smith referred to. He believes based on his years of experience that five percent is a safe cap. We could possibly go back and do some further analysis and see if maybe we can raise it a little bit since as Don pointed out eyewear for the military is allowed to have much higher percent transmittance. So that's something we could do some further work with and look at data that we've generated and possibly also data that Don Smith has generated and speak to some of our other colleagues and see if we can come to agreement.

MS. FAHY-ELWOOD: Okay. And the controls that people would need to see in the bed would be in that blue-green region.

MS. MILLER: Well, that's a good point. Since that cap only applies to the blue-green wavelength region, the controls could be designed so that they were yellow and red. Then they wouldn't be affected. The cap wouldn't affect that.

MS. FAHY-ELWOOD: Right. How about the labelling of eyewear? Is there any requirement for labelling so that people know what they pick up is appropriate for tanning beds?

MS. MILLER: No there isn't. It's so small. The eyewear is sometimes only this big. (Indicating.) There's no room for labelling.

MS. FAHY-ELWOOD: Okay.

MR. SMITH: Well, the Institute is small in answer to your question. We go off the expertise of the Optical Sciences Department at the University of Arizona. That's one of the things they brought to our attention. They're doing a lot of work with cock pit dials. We need to focus some attention on what are the right colors in these buttons so that we can read them easily. Right now we're depending on the light from the tanning bed to see these things. Certainly some creative thought could go in and make them a lot easier.

CHAIRMAN ROTHENBERG: Yes.

DR. BENSON: Something also might be done with voice-activated controls. Certainly that technology has improved a great deal in the last couple of years.

CHAIRMAN ROTHENBERG: Yes, John.

DR. SANDRIK: A question for Dr. Cyr on the definition of the manufacturer. You had indicated I think in part of your discussion about there are performance requirements specified in the standard and it would be a matter of seeing that those performance requirements are still met. In your definition, you do explicitly mention performance requirements as stated in the standard. You also include intended functions. Perhaps that gets into a bit vague area.

As I say there is actually a section in the 1040.2 called performance requirements. There are five things identified. It must do these things. There's nothing really identified as intended functions. I guess maybe that leaves a vagueness here in terms of just where are you going with that. How would you define those? Do you intend to define those, put some limits around what you mean by those? I guess there may be a

vagueness there that makes it difficult to interpret just what might be expected when some sort of modifications are made or perhaps just limiting it as I think you alluded to earlier to those defined items that are called performance requirements.

DR. CYR: A very good point. I'm going to have to defer to our Office of Compliance people who have the expertise and the wording of that particular amendment. I'm not sure what was meant in those particular words. Your point is very well taken unless somebody here from compliance would want to address those two words. Let's just say we will deal with that.

DR. CASWELL: Dr. Cyr, do you have any concern over the wording about the fact that the warning label needs to be legible? Do you think that might be stretched to limits? Do we need to indicate a font size for example? How detailed do we need to get in terms of the warning label?

DR. CYR: That I hadn't thought of. Certainly you want to be able to read it and have adequate light to read it. We had no discussion on size of font or that.

CHAIRMAN ROTHENBERG: Could you just

review exactly where we are in this process and what you're asking us to guide you on?

DR. CYR: Okay. Because many of the comments pertain to things which are coming down the road. I guess they were anticipating that perhaps I was going to bring up those items. Per se I did not bring up some of those things in terms of exposure schedules and the use of an action spectrum other than erythemal. They pertain peripherally to maybe the definition of a manufacturer. Per se we weren't going to present those as new proposals at this particular TEPRSSC meeting.

Right now we were limiting ourselves merely to those things we thought we are ready to go forward with. That was a revised warning statement which is the bulleted one you have. We were focusing on that particularly the language that goes into that statement and the inclusion of that statement into the advertising materials and catalogues, *et cetera*.

The third one was putting language about significantly modifying a product and assuming the responsibilities of a manufacturer. That's requirements that are already in the Medical

Device Act and something that's already been spelled out in the laser standard. We're thinking of putting very similar requirements and language into the standard as it pertains to sunlamps. Not a major change, something that's already there.

The last one was to put things in there about the eyewear. That was the sole things that we were going to present today.

CHAIRMAN ROTHENBERG: Okay. But it sounded like you were going to go back and look at some further things related to the eyewear.

DR. CYR: I think in light of the comments today we need to do that. I also think that between now and the time that we write those proposals that there were some very good comments about who constitutes a manufacturer and what things will be covered about that. I think we can do that within the course of the next year too.

The measurements in terms of measuring a lamp versus the measurements of an entire bed that Don Smith brought up is also something that we've talked about before and pretty much agreed needs to be done. Again that's for things down the road. I have no problem with going forth with those kinds of meetings and determining how one can

measure an entire sunbed.

DR. LIPOTI: I have one more suggestion on the warning statement since you want specifics on the warning statement. I was flipping back and forth between the old warning statements and the revised warning statements. I do think that the bulleted warning statement is much clearer and really helps you to understand.

But there's one phrase that I believe that you have dropped that was in the previous warning statement. That was the phrase "avoid overexposure." It's been replaced by "read instructions carefully." Do you no longer want people to avoid overexposure?

DR. CYR: I think overexposure pertained to the amount of dosage you got not so much about reading. What was the comment you said about reading?

DR. LIPOTI: It says "read instructions carefully."

DR. CYR: Right.

DR. LIPOTI: It no longer says avoid overexposure. That phrase is completely dropped from the warning label. Yet to me that's the real warning you want to give people. Avoid

overexposure.

DR. CYR: We got into a tremendous debate about what constitutes overexposure. I think maybe in terms on the limit of overexposures you don't want people to burn.

DR. LIPOTI: Right.

DR. CYR: So that warning came in there, injury to the skin. I think I do like the comment about maybe per se putting in a warning about sunburn. That may solve the problem of overexposure.

DR. LIPOTI: Do you want them to just read the instructions carefully or obey them?

DR. CYR: I would hope they read them and take them to heart, yes.

DR. LIPOTI: I think I'd like to see something that says obey the exposure schedule or to avoid overexposure. I think dropping that really gets rid of the main purpose for having a warning statement.

DR. CYR: Right. Thank you.

MS. MILLER: The only thing I would say about that is the common person using a tanning bed may not know what an overexposure is. Since if you're getting a burn you don't see it for several

hours, you won't realized that you have been overexposed until much later. I guess we felt that having that in there didn't really add useful information to tanning salon patrons.

DR. BENSON: On the other hand, I think that the public may take this idea of going into a tanning bed as ensuring them against overexposure. It looks so controlled. It looks so scientific. How can they be overexposed? So just having that in the warning label just reinforces the idea that overexposure can happen.

DR. CYR: I think it's easy to define overexposure in terms of sunburn and eye damage, easy but not completely easy because particularly with sunburn it depends on skin type. You can make a wrong guess on skin type and burn somebody thinking that you gave a proper dose when in fact it turns out not to be. This person is much more sensitive than you thought.

Overexposure in terms of skin cancer is another entire thing. Again for the majority of people who never come down with skin cancer, it's not an issue. There's no overexposure. There are unfortunate people who for genetic reasons or what-have-you will end up getting skin cancer from the

sun and maybe from salons. We're less sure about that.

By definition if they got the cancer, they got the overexposure. I wouldn't know where to begin with saying what constitutes an overexposure in terms of skin cancer. I just wouldn't know how to do that.

MR. SMITH: Your questions are apropos. That's why the form that I showed you and the label that going to go on the bed is not going to be read by anybody. It's dark in the room. They go in and get their clothes off. I think these additions that were suggested adding don't sunburn and avoid overexposure are helpful, but it's that client release and informed consent form that we believe that we owe the client the obligation to have them read and sign it before he goes into the tanning bed is what's important. I'll make copies for you if you'd like. It has a lot more information.

CHAIRMAN ROTHENBERG: Yes.

MS. FAHY-ELWOOD: Another comment about the new warning label. The last bullet that talks about the photosensitizers increasing sensitivity to UV radiation. I thought maybe a better wording

for that would be something like certain medicines and cosmetics increase chance of skin injury. The way that the bullet is written now, I don't know if the general public would know what that means. Increases their sensitivity to UV radiation. That's just a thought I had for the group.

Additionally I had another comment about the manufacturing definition. I think that some of the data we saw about the compatibility of lamps feeds into that issue that we're talking about because there could be a salon owner for instance who is changing out a lamp that they believe to be compatible but when in fact they are changing the output of the device. I don't know that those two items are mutually exclusive and that you could wait until the next TEPRSSC meeting to talk about lamp compatibility and come to some consensus on this manufacturing issue today. That's just a thought I had on that.

DR. CASWELL: I don't like the word injury there. The reason why is that in the bullet points we have the word injury. I would be afraid that maybe consumers would see that as it might increase injury but it's not going to increase photoaging. It's not going to increase my risk of

skin cancer.

We know that that's not true. We know that photosensitizers will increase the risk of skin cancer. So I would prefer to keep it along the lines of sensitivity in order to avoid any perception that photoaging or skin cancer are not affected by photosensitizers.

CHAIRMAN ROTHENBERG: We need a motion as to how they proceed. Would you like to?

DR. CASWELL: Yes. I move that we recommend that the revised warning statement as proposed by Dr. Cyr be recommended.

CHAIRMAN ROTHENBERG: Okay. Is there a second?

(Dr. Lambeth seconds by raising his hand.)

CHAIRMAN ROTHENBERG: Okay. Any further discussion on that aspect?

DR. LIPOTI: You mean as is?

DR. CASWELL: Yes.

MS. FAHY-ELWOOD: Then I would still have the comment that I think people might have questions about the last bullet from a consumer perspective. I don't know that it has real meaning for a consumer.

DR. NELSON: You could try may increase your harm from ultraviolet radiation. Would that cover everything?

DR. CASWELL: In a tanning salon, the salon operators are well aware of the possibility of increased sensitivity due to cosmetics and medication. Reliable salon operators actually screen medications prior to allowing somebody into the bed. The risk of sensitization of damage due to UV from sensitizing medicines or chemicals is real. In fact the percent is very low of this occurring. I think adverse drug reactions in the MEDWATCH program point that out.

CHAIRMAN ROTHENBERG: Yes.

DR. LIPOTI: I'm just going to say that I cannot vote for the motion because I think there have been a number of relevant suggestions raised about revising the revised warning statement. I think that the opportunity for a public input here should be taken by FDA. There should be further revision done for the statement.

DR. BENSON: I agree with that. I think that we've made some good suggestions. The countering to what we've raised here is that reliable salon owners have that in hand. I'm

thinking more of the label that goes on a box that someone takes home and sets up a tanning bed in their garage. So we need to make the warning label relevant to that person, not so much to the tanning salon owner.

MS. LOSCOCCO: I have to agree with that because I think it's a two-fold process. I think the tanning bed salons have it under control. What we're trying to also make sure is that the owner understands.

CHAIRMAN ROTHENBERG: Well, the proposed rules are not yet -- So maybe we should recommend that there be a revised warning label, and it also should take into account the various suggestions. Then we'll see what they come back with. Can we accept that as an amendment?

DR. CASWELL: Sure.

CHAIRMAN ROTHENBERG: So then with the amended proposal, any other comments?

(No response.)

CHAIRMAN ROTHENBERG: All in favor?

(Chorus of ayes.)

CHAIRMAN ROTHENBERG: Eleven in favor, none opposed. We've lost one of our members. Now with regard to other aspects of the presentation.

Does anyone want to make a motion? Dr. Cyr has indicated that they would take into account a number of the suggestions made already with regard to modifications, equipment, what constitutes a manufacturer and other aspects of what he's presented. Do we want to make any further motions?

DR. NELSON: I don't know if I want to make a motion yet but you've mentioned that you would look into this idea of modifying the eyeglasses, eye goggles, transmission spectrum. It sounds like it's important that people be able to see the controls, and yet it's not clear to me that this higher level that people are talking about is safe. I'm wondering if there's some level ground perhaps that will go with the five percent transmission right now with the idea that perhaps another regulation down the road would be that the manufacturers put the controls in different colors. I guess my question would be is it too premature to move on the eyeglasses issue.

MS. MILLER: Well, I guess one option is that we could move ahead with the five percent and when the proposed rule is published in the Federal Register which will still be quite a ways away, anyone can submit comments and data if they

want to oppose that or support it or argue against it. We could go ahead with five percent and then once we get comments back there's still time to revise that if we feel there's enough evidence that we could go a little higher and still be safe and provide a safe pair of eyewear for the consumer.

DR. LAMBETH: On the eyewear and the visible transmissions, it seems like the objective is the simply allow the user to be able to see and yet not be so bright inside this box that one is blinded by it. I don't have a perspective on these bulbs as to really how bright this is from a practical standpoint. I must admit I've not been inside one.

If someone came along with a new bulb that met all the UV standards to produce tanning without harming but actually had a very bright or extremely bright line in the visible, it seems like your standards go out the window. They're no good if there was actually a line at the 500 nanometer region. Specifying transmission without knowing what the bulb puts out doesn't seem to be the appropriate way to do it. I know where you're coming from. I understand your logic.

MS. MILLER: Yes. It's very difficult

to do an analysis for every conceivable type of light source. We can only base it on what we know is the worst case condition right now.

DR. LAMBETH: Maybe you could just inform me a little bit. If I have a five percent transmission at 500 nanometers, how bright is it? Is it comparable to this room?

MS. MILLER: No. It would be much dimmer.

DR. LAMBETH: It's much darker. Right?

MS. MILLER: It's five percent so it's reducing the light that you're getting from these sources down five percent.

DR. LAMBETH: No, but I'm inside the bed. The light inside the bed is much brighter than these lights.

MS. MILLER: Right. So you're saying how much would you be seeing.

DR. LAMBETH: Can I see as well as I can see you right now?

MS. MILLER: I don't think so. I actually haven't done that test. I would say it's much dimmer. Maybe Don or someone who's done a lot of testing --

DR. LAMBETH: Is it equivalent to

turning all the lights out here except for the ones by the door? I don't have a perspective. I'm just trying to get a perspective.

MS. MILLER: I can't tell you specifically but it's fairly dim. You don't want it to be too bright because of the potential hazards. It's just supposed to be --

DR. LAMBETH: This is visible. There's no hazard in the visible to speak of. Right?

MS. MILLER: No, there is a hazard actually to the retina from visible light.

DR. LAMBETH: But it's visible light. My eye is designed to look at the visible light.

MR. MYERS: Let me say something, Dr. Lambeth.

CHAIRMAN ROTHENBERG: Could you please identify yourself.

MR. MYERS: I'm Dave Myers from Light Sources. I have in fact been inside of a tanning bed before. I can tell you that my analogy would be it's similar to wearing welder's goggles if you've ever looked through welder's goggles.

DR. LAMBETH: Yes.

MR. MYERS: It's very similar to that. It's very dark.

DR. LAMBETH: I can't see a thing through welder's goggles until I strike an arc.

MR. MYERS: Well, exactly. If you have a bright enough light source, you can still see. It would be to me like welder's goggles. Most of these beds are in the order of 2,000 watts.

DR. LAMBETH: Okay.

MR. MYERS: Does that mean something to you?

DR. LAMBETH: Yes.

MR. MYERS: It's relatively bright. Much brighter than the chandelier. Don't forget your face is only inches away from the bulbs.

DR. LAMBETH: So when you're saying it's like welder's goggles looking at a welder's arc.

MR. MYERS: Yes.

DR. LAMBETH: Okay.

MR. MYERS: I personally don't have any problem seeing controls with the current standard as it is right now.

DR. LAMBETH: I would say for those who haven't welded. That's sort of the equivalent of turning out all the lights in here except for the ones along the wall. Wouldn't you agree?

MR. MYERS: I don't know.

DR. LAMBETH: Something on that scale.

MR. MYERS: Yes.

DR. SANDRIK: It sounds like maybe even there's an evolution going on here in how these tanning beds are devised because it sounds like from an answer to an earlier question that these controls were lit up by the sunlamps. There was a very high level of illuminance on the controls so you could have a fairly dark opaque kind of eyeware and still see the controls.

Mr. Smith has mentioned that they're moving the controls into a more darkened environment. It seems in that case then you have to readjust the transmission or transmittance that you allow based on the illuminence of the controls. Maybe it's not the preferred thing but it gets back to what's the purpose that you want to achieve or perhaps linking the eyeware to the source. With this source you have to be able to get a certain level of transmittance for the illuminence of the controls or something. It probably just complicates things. It sounds like a specific transmittance may be going too simplistic for the variety of equipment out there.

CHAIRMAN ROTHENBERG: I think Mr. Levin has something.

DR. LEVIN: Bob Levin again. A couple of comments. One is with regard to welder's goggles. They're often an optical density of six which means about a 10,000th of one percent. That's a far cry from what's proposed here.

More important, I think Sharon made the key comment when she said the standard was set by the high pressure discharge lamps because those are very compact, very high radiance, and they are an extreme hazard. If your eyes were not protected, it would be like looking at the sun with the consequences following along.

Probably two standards could be used. One would be for flourescent systems where you do not have this extreme hazard. The other would be for the discharge lamps. Also it's not completely adequate to talk about military requirements on sunglasses because you still have the aversion reflex. It would not protect you against sunlight. People generally can't stare at the sun.

In the bed with a very high intensity source immediately in front of the face, there's no way to control and prevent people from doing that.

There are standard safety requirements, various ANSI standards that will let you determine the hazard from any given source. These can be applied to determine a safe level.

CHAIRMAN ROTHENBERG: So it just seems like you have to look into this further particularly with these discharge lamps to see what the problems might be. In addition with trying to harmonize with the other regulation, you need to look at that.

DR. CYR: And it looks like we need to go back to the international community with the things that we've heard here. They need to know that input too.

CHAIRMAN ROTHENBERG: Yes.

MR. PLEASURE: Again, I reflect on how this particular change is connected to the overall regulatory scheme that you have in the sunlamp regulation where you have a warning label which now is required to be affixed in the place that will be seen by the person to be exposed immediately before exposure. We hear now that the room is dark and you can't see it. So the way people are operating and they're basically getting undressed, they can't see it. Apparently Bob Levin is correct there's

non-compliance as a matter of practice with the existing regulation.

Then there's an additional requirement that instructions to the users be distributed at cost by the manufacturers. We're working with very limited devices to obtain a result. We have a darkened room. We have a warning label that apparently can't be seen. The practice is to give the person a release in some cases. They sign off on the release. That contains some information.

Yet there's no regulation requiring that the person to be exposed get that kind of detailed explaination. Maybe they should. Maybe they should get what every construction worker can get which is a material safety data sheet on a product that they're going to be installing in a building and that's present on the job-site so they can go look and see whether this particular product presents hazard and what to do about the hazard.

I ask that when we take up an issue like this that it be linked up to the various other pieces of the regulation; in this case, manufacturers instructions, the existing regulation that requires that it be affixed in such a place that it can be definitely seen immediately prior to

use. So that it all fits together for us and we can determine whether it's achieving its result and whether something more might be required.

In this case, I happen to think that what's required is something like what Bob Levin was talking about, that you give the person a piece of paper that has some detailed warnings and some explanations on it. You make sure that they read it before they lie down and they're exposed in this darkened room rather then relying on them to spot this thing on the machine or the manufacturer to somehow get to the user enough information which may now be lost. Let me stop at that. I think what I'm asking for is some more contextual discussion so that we can see how this really works which Bob Levine was trying to provide I thought.

MR. SCHUSTER: A couple of comments. Joe Schuster again from Light Sources. I think what I would encourage all of you to do is step into a tanning salon. I'm getting the image that you have somebody that's fumbling around in the dark and can barely see. That's not the case.

By the standard, you have to have that warning label clearly visible at a particular distance on the front of the bed. It can't be

hidden. It's not behind the bed. It's clearly legible on the front. In addition to, salons then have a client warning statement that they have to read these people to show them the hazards as well which is a replication of that warning label that's on the bed. There are a variety of measures. They're not walking into a dark room where they can't see anything. I don't agree with that analogy.

MR. PLEASURE: I was just repeating Bob's --

MR. SCHUSTER: Okay. I just want to make it clear so that we all know. Go to a tanning salon and see how it's done in actuality. In the reality of it, they're not darkened rooms. You can clearly see the warning label. Find out how a salon owner would take you through the various hazards because people that tan don't think that there are any hazards. They realize it. It's in clear print right in front of their face.

MR. PLEASURE: Now it's your understanding that the person under the regs must be supplied with a copy and read a copy of the warning regulation or is it only visually present.

MR. SCHUSTER: It's visually and

audibly. They are reading it to them and they see it on the warning label.

MR. PLEASURE: That's good. Is that required by the regulation now that they read it to them?

MR. SCHUSTER: The standard supports that the warning label be on every bed. I guess you could say that the industry takes it a step further and shows them this warning statement in writing and has them sign off that they've read it.

MR. PLEASURE: That's good. Maybe it should be required across the board.

MR. SCHUSTER: Not a bad idea.

MR. LEVY: I just wanted to concur. I'm Joe Levy from Indoor Tanning Association. The standard educational protocol in the industry today is to walk the customer through and show them the equipment, show them how it works, and show them the warning label. That is a standard operating procedure.

CHAIRMAN ROTHENBERG: So if I went to a tanning salon, what would be the probability that it would happen?

MR. LEVY: On your first visit, you'd be shown the entire facility and how the equipment

works, how you are to use it, what the warning label is. As Joe mentioned you are already given a much more specific consent form to sign that has the same language as the FDA warning label that currently exists.

CHAIRMAN ROTHENBERG: Are you saying this would be true at 95 percent of the places I went, 100 percent, 80 percent, 20 percent?

MR. LEVY: I think that's going to be true at any professional facility. I don't have a number for that. A salon would be foolish to not have someone sign their consent form just out of a liability situation.

CHAIRMAN ROTHENBERG: Maybe one more quick comment on this.

MR. SMITH: Maybe some of the confusion comes to answer your question is that the FDA regulations are to the manufacturer. The tanning salon owners are under the jurisdiction of the state regulatory agencies. Most of the regulated states require that these informed consent and client release forms be used. So that's a state reg.

DR. CASWELL: I'm probably the only panelist who's been in a tanning bed before. My

experience mirrors what Joe Schuster said. You go in. You take off whatever clothing you'd like to take off. It's well lit. You get all the controls set. There's a button that's available.

When you're ready, you can turn it on. Before that happens, I set everything up. I get my goggles or eyeware in place. Then I reach up and I turn on the on button. I stay there until it's off. As soon as the machine shuts off then I take off my eyeware, get dressed and leave. It's not in the dark. I've never seen a darkened room. I think that's a misrepresentation that somehow you're fumbling around in the darkness. I think it's a well-lit environment. I think the controls can be set well before you turn on the bed. Does that help at all?

MR. PLEASURE: It does help me but let's be clear that one of our witnesses was reflecting on this, not the Committee. I think if he's reflecting that it is a common experience then what you described may be optimal and what he describes may be something else. That raises a question as to the necessity of regulation that incorporates some of the best practices that go beyond simply affixing a label.

That may require giving the person an informed consent form. It may require that it be read to them if that's the practice. It doesn't sound like the industry in general would be opposed to that. They're doing this now they say.

DR. CYR: I was going to attempt to clarify but maybe I would only confuse. I think what they were saying is it's dark inside the canopy, inside the bed to look at controls out there, not outside in the room. It's once you're inside the bed with your eye goggles on, then it can be dark and you may not be able to see controls which are already inside the bed. These are new gadgets that they have inside the beds. The warning statements and labels are outside on the outside of the machine and the room is lit.

MR. PLEASURE: Yes. In practice apparently they're read to the people. They have an informed consent form. None of which is required now under the existing regulations. It might be advisable having discovered this optimal practice. We wouldn't be so anxious then about the very limited parameters of the warning label. If there was more information provided on the equivalent of an MSDS that I'm familiar with for

workers then the consumer could be protected by information that was more adequate than just a label.

DR. CYR: I think it was Don Smith who said the actual regulations of salons is done at the state and local level. We have worked as I said in my presentation with the Conference of Radiation Control Program Directors. They have a suggested state regulation and as part of that they have these informed consent statements. I think it is something we should press the states to do.

MR. PLEASURE: Yes. But right now the manufacturers are required to have produced a detailed set of instructions. The manufacturers are required to have a label that must be readily seen by the person to be exposed. So what you say that the FDA has not taken up the issue of what experience the person has and that the FDA doesn't take cognizance of what the manufacturer must do that relates to the user is not so. The regulation does get into those issues right now.

MS. LOSCOCCO: What percentage of states have regulations that would apply? What percentage of tanning beds are owned by just single-users?

DR. CYR: I can let somebody else answer that who knows it exactly. I think it's a little over half the states. It's 27 states. The second part was what?

MS. LOSCOCCO: How many beds are just owned by single-users?

DR. CYR: How many home units are there?

MR. LEVY: I won't go to home units. I let someone else answer that. I'm Joe Levy again. We did a survey last August of compliance because I know where you're going in states with whether or not their customers are sunburning and whether or not they're complying with the main rules that are pretty much set up by what the FDA requires the manufacturers to stick to; eyeware, sunburn, the exposure schedule and that type of thing.

What we found is that compliance is just as high and success rate is just as high in the states that don't have these supplemental regulations. The industry is doing a great job of self-regulation. We agree with these standards. Obviously as I mentioned from a liability standpoint we are getting that warning statement to customers.

I disagree with the assessment made earlier that the customer is not seeing that warning label because that's part of the protocol that we teach in our education courses that are at the industry. It's part of the protocol to show them how the bed works and show them the warning label. So we're doing that ourselves.

CHAIRMAN ROTHENBERG: Okay. I think what we're going to do now is to take a break at this point. We can have some further discussion this afternoon. We're getting way behind schedule. We're going to take a lunch break now with possibly one brief comment by Dr. Cyr.

DR. CYR: Question. You said additional questions. Would that be when we come back or after the next presentation? When we come back, we'll finish up sunlamps?

CHAIRMAN ROTHENBERG: Yes.

DR. CYR: Because some of the people here are anxious.

CHAIRMAN ROTHENBERG: We'll have a brief period when we come back.

DR. CYR: Because they're not anxious to sit for the whole next presentation.

CHAIRMAN ROTHENBERG: Right. No.

We'll do that before we get to the people scanners.

DR. CYR: Okay.

CHAIRMAN ROTHENBERG: So please reassemble at 2:00 p.m. instead of the initial schedule of 1:45 p.m. Off the record.

(Whereupon, at 1:02 p.m., the above-entitled matter recessed to reconvene at 2:05 p.m. the same day.)

CHAIRMAN ROTHENBERG: On the record. I'd like to call the meeting to order again. I'll also remind any of you that may have come in late if you didn't sign in on one of the sheets outside the door, we would appreciate if you would do so. That way we will know who was here and whom you're representing.

It seemed like as we broke for lunch we had pretty much given Dr. Cyr and his group -- There was a lot of discussion. They agreed to take things under advisement as they proceed forward and then will come back with revisions. So I think unless there is some really urgent comment, we'll proceed with the rest of the meeting. Yes.

DR. NELSON: Actually I would like to ask Dr. Cyr a question about the goggles. Then hopefully we can move on.

CHAIRMAN ROTHENBERG: Okay. One question about the goggles.

DR. NELSON: Yes. My question is my understanding is you picked this five percent transmission level because you have good or at least reasonable data to suggest that's a safe level. If I heard testimony correctly earlier today, my understanding is there are goggles out there now that no longer meet the old Federal guidelines. Is that right?

MS. MILLER: Yes. The five percent which is in the IEC standard was based on some analysis done by an engineer at Philips Lighting using a 400 Watt high intensity lamp. That showed that if you had a five percent limit with that type of light source, you would be below occupational safety levels for retinal damage. Like I said, it's not really a fine line between a safe and dangerous exposure, but we feel it's a practical number.

DR. NELSON: Okay. So if we don't pass your resolution, it's possible that there would be eyeglasses out there that would have higher transmission, and we don't know the safety about those. Is that true?

MS. MILLER: Yes. And they're already are eyewear out there that have a higher transmission.

DR. NELSON: That seems to me not an ideal situation.

MS. MILLER: Currently the FDA standard doesn't have any limit on the visible transmission. That's why this has occurred. I don't know how much testing is done in other countries. If they are sold in other countries, they are supposed to meet this five percent limit. It's a very small percentage of tanning beds that have these high intensity discharge lamps. That's not a huge problem, but we would like to incorporate something in the standard that would ensure safety.

DR. NELSON: Yes. So my understanding is if we pass this resolution today, you still have some procedures that you would go through. It doesn't close the door on potentially upping the threshold at another time. Is that right?

MS. MILLER: That's true.

CHAIRMAN ROTHENBERG: Right. The idea was that we were going to go back and look into this further and also look into the special problems associated with the high pressure, high

intensity lamps.

MS. MILLER: Yes. But what she's asking is if you were to approve five percent, that wouldn't preclude us changing that before it goes to a final rule which is true.

DR. NELSON: Yes.

CHAIRMAN ROTHENBERG: Do you have something?

DR. SULEIMAN: Yes. Just to clarify. That's exactly right. We're in the rules making process. This is still way ahead. If you were to formally recommend and we bought into very specific wording and then three weeks later or two months later we learn some new things, then some people say should we change it, shouldn't we change it. I think as long as the issues that the Committee has raised are considered and even after we come out with the official proposed rule, then we go to this 90 or 120 day comment period. Then we have the opportunity or option to change even then. We're way ahead of the curve. I think a simple go or no go type recommendation would be appreciated by us.

DR. NELSON: Okay. All right.

CHAIRMAN ROTHENBERG: Do you want to make that motion?

DR. NELSON: Okay. I think what you're asking me is to suggest that we --

CHAIRMAN ROTHENBERG: That they go ahead with the proposed eyeglass standard pending. Unless there are reasons to change the limits based on knowledge of what we gain soon.

DR. NELSON: Okay. What you said.

CHAIRMAN ROTHENBERG: Okay. Does someone want to second that?

DR. BENSON: Second.

CHAIRMAN ROTHENBERG: Okay. Any further discussion?

(No response.)

CHAIRMAN ROTHENBERG: All in favor?

(Chorus of ayes.)

CHAIRMAN ROTHENBERG: Eleven unanimous. Eleven for. Okay. The next item that was on our agenda was a welcome from Dr. Feigal, but he's unable to attend this afternoon. We will then proceed with the next item of business which is the Personnel Security Screening Systems. Mr. Cerra will present. We thank you all who are leaving for your interest and input.

MR. CERRA: Good afternoon. I am Frank Cerra from the Office of Science and Technology of

CDRH. I will be speaking about products to x-ray people for security reasons, better known as people scanners. The presentation will be in two parts. I will first give an update on the progress on a consensus standard. Dan Kassiday will follow with some discussion on new systems and new developments.

The consensus standard is the American National Standards Institute N43.17, Radiation Safety for Personnel Security Screening Systems Using X-rays. I am glad to announce that the standard has been approved by ANSI and adopted as of April 2 of this year. I would also like to thank this Committee for its role in spurring this project.

The products that are covered by this standard have been in use in this country for several years. The one that's pictured here is the Secure 1000 model. It consists of an enclosed cabinet. The person is asked to stand in front of it, and a narrow beam of X-rays scans left to right, top to bottom.

It works on backscatter technology, that is, there are radiation detectors behind the front panel which sense the radiation that's

scattered back from the body into the cabinet. Then a computer image is generated. Typically the individual is asked to turn around and a back view is taken.

This is another model, the Bodysearch by another manufacturer. Again, it works on the same principle. The backscatter units are very efficient at looking through clothing. You can imagine there are some concerns about privacy as well as the radiation safety concerns which we are interested in. Also backscatter imaging is not very useful for looking at objects inside the body.

A summary of the chronology of events leading up to the standard. Back in September 1998, there were several presentations before this Committee on this subject. The members had enough radiation safety concerns to recommend that FDA adopt a mandatory performance standard to cover the products. One of the main concerns was that there might be an escalation of the dose levels to the general public if the technology went unchecked.

FDA considered the recommendation very carefully. We considered the public health risks involved and weighed that against the available resources and other Center priorities. At the time

we decided that maybe FDA could be most effective by promoting a consensus standard rather than writing a mandatory standard.

There were some advantages to the consensus standard. In the first place, we thought it could be completed sooner and be in place in a timely manner. Also, we could include requirements for the user facilities whereas a mandatory standard from FDA could only include performance standards relating to the product. In addition to that, if a mandatory standard was deemed to be necessary at a later date, we thought we can take the performance requirements from the consensus standard and incorporate them into the mandatory standard.

In April 1999, we proposed a new project to the ANSI N43 Committee on non-medical uses of radiation. The project was approved. In November of that year, the newly formed N43.17 Task Group convened for the first time. In June 2001, we had a draft standard which we submitted to the main committee. Finally, we received final approval from ANSI in April of this year. The standard is due to be published on the Health Physics web site shortly.

The next three slides summarize the main requirements of the standard. The standard is innovative in that the dose limits for the subjects are in terms of effective dose. Effective dose was defined by the International Commission on Radiation Protection in the ICRP Report 60.

It takes into account the risk to the whole body based on the vulnerability of key organs from a known exposure condition. There are a list of 12 key organs. We thought that is really the quantity of concern. We also thought that we could make accurate measurements and assess it properly for these types of systems. So we used it.

The first limit is a maximum dose of 0.1 microSieverts per scan, that is, per scan from the front. The reason for the limit is that it was what the technology can do easily. We didn't see any reason why we should increase the risk to the individuals being screened.

The second limit is 250 microSieverts per year from one facility to any one individual. That is based on the National Council for Radiation Protection and Measurement's recommendations of NCRP 116. The idea behind the second limit is that the general public should not receive 1,000

microSieverts of radiation from non-medical, man-made exposure from all sources in a year. It's limited to 250 from one source.

That may present some problems when you have more than just a few known sources. If these things were to show up at many different places then there would be some problems with that limit.

Also, another benefit of the per scan limit is that the second annual limit is more difficult to assess compliance with than the first limit because you need to keep track of individuals. As you can see, it takes 2,500 scans to reach the annual limit. That's seven scans per day. You only need to consider those individuals who show up at the facility very often, several times a day. That's an additional reason for the first limit.

The standard requires that there be a benefit from every exposure. This is an intentional non-medical exposure. It better be needed. In this case, the benefit is security. We also require that subjects are informed that X-rays are involved and the dose that they're getting. They need to be given an understanding of the

associated risk based on a comparative example.

The standard has a radiation leakage requirement that is similar to the requirement for cabinet X-rays in the mandatory standard. It's 2.5 microSieverts per hour at 30 centimeters from the surface. This is not including the front surface where the primary beam comes out of. This is not effective dose but it's entrance skin dose.

For bystander protection, the standard requires that an inspection zone be identified and well marked. People other than the person being scanned are not allowed to be in the zone at any time. The maximum limit outside of the zone is 20 microSieverts per hour.

We have requirements for safety interlocks on all access panels to the interior of the cabinet and also operational interlocks in case the beam should stop moving. This standard also has a requirement for a label which identifies the product and requirements for indicators and controls, the main ones being that there must be a lighted indicator to show that the scan is in progress. By the way, the scan lasts about five to seven seconds, maybe less. This indicator should be visible from anywhere close to the inspection

zone.

We also have a requirement that the exposure technique factors, kilovoltage, mA and so forth, must be fixed for any mode of operation. The reason for that is we didn't think that we could require a certain level of sophistication from the operator of these systems.

There is a requirement for operator training listing a number of topics that must be covered by the training. There is also a requirement that the operator demonstrate proficiency upon completion of the training. Also, there must be annual refresher training.

The requirements for records to be kept by the manufacturer are similar to the ones required of cabinet X-ray units. Mostly they are for keeping track of products in case there should be a recall. The user facility is required to keep records to show that they conform to the standard, for example, the results of periodic radiation surveys and also a list of individuals who may exceed or approach the annual limit.

Besides the normative requirements of the standard, we have two appendices that are for information only. The first appendix is a

discussion of radiation risks and the rationale for those limits in the standard. The second appendix is a discussion of measurement techniques. It includes a measurement protocol for measuring the exposure or air kerma (PH) and then a protocol for converting that measurement to effective dose.

In order to do that we had to generate some charts with conversion coefficients. These were derived from the conversion coefficients published in ICRU 57 which are for monoenergetic sources. The chart allows the conversion of a measurement of exposure by simply knowing the kilovoltage on the tube and the total aluminum equivalent filtration. The first chart is for a front scan. The second chart is for a rear scan.

The measurement protocol was tested at several facilities. The photos illustrate one of these tests at the Customs facility at Los Angeles Airport. As we look at the next two slides, I will ask Dan to step up to the podium.

MR. KASSADAY: Hello. I'm Dan Kassaday with the Office of Compliance. Several months ago the Center for Devices and Radiological Health received a submission for a product intended to detect contraband concealed within a subject as

well as under the subject's clothing. We are bringing this product to the Committee's attention because the subjects receive a significantly higher dose than from the previously discussed backscatter systems which are exclusively for under clothing analysis. During this talk I plan to describe the product and CDRH's proposed response. We look forward to your discussion and advice regarding our proposed response after this talk.

This is the product that we received the submission for, the Conpass Body Scanner. It's a transmission X-ray. The tube is under the operator's desk underneath the monitor. It goes through the fan collimator. It goes through the subject who stands on the platform with the handles here. That moves them across the beam.

These are some example images. As you can see, you see all the way through unlike with the backscatter systems. The system has a roughly equivalent scanning time. It's peak tube potential ranges from 70 to 200 kilovolts. Both the tube potential and the tube current technique factors are adjustable. A dose to a subject is five microSieverts as reported to us although I'm not sure that's effective dose. We've received at

least one or two other inquires about similar systems but have not received any reports at this time.

This mission identifies the intended use of this product as passenger control; security at airports or train stations and similar facilities. The advertising however included with the report indicated that there are many other places where this type of system might be used, for example, diamond mines. In a brief discussion with a regulator from South Africa, they do indeed have three different systems in use there as well as backscatter units for the diamond mines.

It could possibly be used in prisons. The backscatter units have been used in prisons for checking visitors to the prisoners. It has been used by U.S. Customs on people coming into the country. But it's a choice between the backscatter and a pat down search. This advertising goes on with the idea of public offices and banks and stadiums and all sorts of other facilities might be appropriate for it. Proliferation of this type of product would no doubt lead to individuals receiving multiple doses from it.

Other products might expose people near

them to incidental radiation. These products intentionally expose people to ionizing radiation. Based on the linear, no threshold model of radiation risk, any increase in your dose results in an associated increase and a risk of an adverse health effect. Unlike medical X-ray, the dose from these systems provides no direct benefit to the individual being examined. Therefore, the use of these types of products must be justified only if there is a sufficiently large societal benefit from their use, for example, security.

Our response to all of these products intended to X-ray people for security purposes has been based pretty much on these four principles. In turn, the first two principles are based on recommendations from the National Council for Radiation Protection and Measurement from their report 116: Limitation of Exposure to Ionizing Radiation which was published in 1993.

The first principle is that below a certain point doses become negligible and aren't worth tracking for cumulative dose total per year. The NCRP set that as a 10 microSievert cumulative dose for one year from one source of practice. A practice that results in individual doses that are

less than negligible individual dose, but that will be probably used enough times in a year to exceed the 10 microSievert limit cannot be considered to be negligible. NCRP also recommends a 1,000 microSievert per year annual limit for any doses that are continuous or frequent. This recommended limit applies to all doses that are not from medical or naturally occurring sources.

Additionally we believe the evaluation of the benefit from such a system will require understanding of the security threat being averted as well as the risk from the radiation being used to detect that threat. Of course we expect that any product that exposes people to ionizing radiation intentionally will be designed and operated to ensure that the dose is as low as reasonably achievable to product the intended benefit.

Just a few more details about the negligible individual dose. That's the basis for where NCRP set the dose based on measurement difficulty and the magnitude of the dose. For comparison, average background radiation results in a dose of approximately 3,000 microSieverts per year. This is 300 times the negligible individual

dose. Negligible individual dose is 100 times the limit set in the ANSI N43.17 standard of one-tenth of a microSievert per front exposure.

Hypothetically 101 exposures to a product that meets the ANSI standard would result in exceeding the negligible individual dose. It would require 10,000 exposures from such a system to reach the recommended annual limit of 1,000 microSieverts.

The transmission units which provide internal inspection as well as external are being compared to the backscatter units which are essentially an under clothing search. But because it's transmission or because it's backscatter isn't the reason we're developing a new response. They're merely convenient descriptors for existing products.

We are developing a new response to transmission products because of the increased dose and other associated increases in complexity of the product. For example, a transmission image is significantly more complex. The system submitted has adjustable technique factors unlike the fixed ones for the backscatter units. It's approximately 100 times more dose to each subject for each scan.

Where we are today. FDA as we've discussed earlier today doesn't have the authority to regulate the use of these products, only over the manufacturers and product performance. None of these products are regulated as medical devices. They are all products that are electronic products that emit radiation and are covered by Title 21 1010 through 1050. At this time no Federal performance standard applies to these products.

FDA's proposed response to the transmission systems is to develop a guidance for manufacturers of all of these types of systems, take the recommendations for user safety and safe use probably based on N43.17's recommendations and publish that as a safety recommendation, develop a mandatory performance standard which will include dose limits and other performance aspects that will apply to all of these types of systems. We're in the process of encouraging new instruments to be developed both for these systems and for cabinet X-ray to allow easier field testing of all these systems. We would like to work with the states to possibly establish use regulations in the suggested state regulations through CRCPD.

The proposed standard as I said will

have a dose limit, will include a discussion of interlocks for beam motion or in the case of other systems motion of the subject, labelling, indicator lights, controls, *et cetera*. Fortunately, N43.17 laid the groundwork for a good starting place for any kind of discussion on those.

The evaluation of benefit versus risk requires that people analyze the threat being avoided versus the threat to public health from the radiation risks needed to thwart the security risk. A possible questions that needs to be asked when considering this risk/benefit equation would be is there a sufficient increase in the quantity and the quality of the information developed to justify the increase in dose. Appropriate use of these sorts of systems requires consideration of the population dose, possible retakes and the potential for many exposures occurring as these products proliferate. These are just a few ideas to maybe spur your discussion. Thank you.

CHAIRMAN ROTHENBERG: Okay. Thank you. Questions from the Committee for either of our presenters?

DR. LAMBETH: Do I understand --

CHAIRMAN ROTHENBERG: Oh, okay. We're

also going to have a member of the public give a short presentation. Maybe we should have that too. Sorry. This is Mr. Tom Wiggins.

MR. WIGGINS: Yes, sir. Thank you.

CHAIRMAN ROTHENBERG: Tom Wiggins from Compass.

MR. WIGGINS: And I have extras of those as well. I apologize for speaking so loud. I have a loud voice. I do have 30 extras so there are enough.

CHAIRMAN ROTHENBERG: We need one more for the Committee if possible.

MR. WIGGINS: Good day. My name is Thomas J. Wiggins. I represent X-ray Equipment Company of Miami, Florida. Thank you to the distinguished members for allowing my company to discuss with you a revolutionary security body scanner labelled Conpass. Conpass to signify Controlled Passage. My primary objective today is to briefly describe operational use while by colleague, Keith Carter, will use his expertise to discuss our field-based established standards to control the emission of the electronic product's radiation.

The Conpass security body scanner is a

revolutionary digital technology for low-dose radiographic security scanning. It has been developed as a spin-off of a low-dose medical radiographic device. The Committee will no doubt learn more about this device in the coming year. Truly the Conpass technology will prove to extremely lower the health risk from X-ray use while simultaneously improving security at our nation's secured locations.

The principle operation of Conpass is based on the use of a very narrow collimated low-dose X-ray beam. A highly sensitive, linear, multi-element semiconductor detector then receives the low-dose X-ray beam and downloads its output to a proprietary software interpolation and enhancement process. Within ten seconds of the start of the scan, a full head-to-toe, high-resolution, low-dose X-ray image displays on the operators workstation allowing for the identification of metal as well as non-metal items externally or more importantly, internally with no privacy issues for which competitive technologies are being criticized.

Our work in Washington on political fronts has labelled the internal threat of plastic

explosives as real and credible. This type of verification of hidden internal threats from plastic explosives is the driving force for the Transportation Security Administration to desire to conduct testing of the Conpass to overcome this menace to aviation security.

In the words of Aviation Subcommittee Chairman John Mica from a "Crossfire" interview on CNN, "We're facing a new type of terrorist threat. And we found terrorists are willing to blow themselves up. And they can conceal explosives even within body cavities. So we're going to have to have equipment that will detect those explosives if we want people to be able to fly with security and safety."

The United States Government is proving they will not overlook any possiblity of threats, internal or external. The tragic, unthinkable events of September 11, 2001, guaranteed that we as a nation need to be aware of all devious possibilities that are at a terrorist's disposal.

No average individual would have ever dreamed that four planes could be simultaneously hijacked and flown into buildings as missiles. It is unfortunate that this event opened the eyes of

the World. However, it is our mission as a technology vendor to try to overcome all future events while keeping the American public informed and safe with regards to ionizing radiation.

Currently, we are working on a nationwide PR campaign to educate the public, politicians, and policy makers concerning using our new technology to overcome the threat of internal plastic explosives. Our equipment has been compared to the "shoe-fitting" machines of the past. Unlike those unregulated devices, we have already implemented radiation control measures to prohibit the reckless use of ionizing radiation.

In addition in the past eight months, the position of the FAA was that "they" felt that the American public would not tolerate being exposed to radiation for security. However, our initial polling shows overwhelming support for using new technology, radiation included, to overcome the threat of terrorist activities. We cannot underestimate the American public by comparing our new technology to older, unmonitored, higher dosage equipment. It is a new world which requires new standards and monitors.

The current radiation security devices

on the market, ours included, do not have the same in-depth requirements of the medical arena. We welcome the interaction of the FDA to provide improved and more in depth standards for our industry. This accomplishes two goals: (1) Improved safety for the individuals being scanned and (2) higher acceptance of the products by the American people, thus improving safety of the secured areas due to lower resistance to use.

We are here today to help initiate the standards of this Board within the industry. The technology of Conpass has been tested and deployed in over 51 locations worldwide. It currently holds Health Certificates in France, Germany, Belarus, The Netherlands, South Africa, Saudi Arabia and Kuwait. The system is in daily operational use by airports in France and Africa, diamond mines in South Africa and government buildings in Saudi Arabia. India has requested a substantially larger order for all facets of security in their country.

Again, thank you for the opportunity to address this FDA Committee, and we are available for questions at anyone's request. It is now my pleasure to introduce to you Keith Carter who has headed up the validation and electrical safety

testing conducted by Intertek Testing Services and radiation testing conducted by Dr. Gossam Jamshidi of New York.

MR. CARTER: First off, I would like to start my statement by thanking the Board for allowing us the opportunity to address this growing issue in America. We as a nation are facing more and more threats of terrorism every day, some cannot be caught and stopped. However, most that would occur at a secured location such as an airport can be prohibited. The Conpass, we feel is the product that can accomplish that task. However, we are aware of the issues with radiation, and we want to do all that is possible to educate and to eliminate those fears.

The way to overcome the fears of both the FDA and the public is to aggressively pursue the following avenues: (1) education and training of the operator, (2) hardware safety measures, and (3) software safety measures. I would like to briefly speak a little more in depth on the standards we have set for each of the above.

On number one, education and training of the operator. It is imperative to have mandatory training and education for all operators

of the Conpass device. Just because radiation has a stigma already attached to it with the public, we must be diligent in our efforts to be professional and intelligent with the use of this product.

Based on field use and development outside of the United States, training and re-certification of operators is required. We have put in place a 40-hour initial team based training and certification for the Conpass device. The mandatory minimum operator qualifications are as follows: (1) a high school diploma or equivalent GED, (2) one year as a security screener in the airports or in the jails or whatever the facility may be, and (3) accomplishment of current and future Federal guidelines regarding background checks.

The 40-hours are then broken up as follows. Day one is an instructional course of what ionizing radiation is and what it can do to the human body if used inappropriately. Day two is focusing on anatomy training. Since we perform internal searches at a skeletal level, we must train the operator as to what they are looking at. A radiological background is not necessary as we do not show individual organs. Day three is a

breakdown of what the Conpass consists of on a components level, and how the safety measures of those components fit into operational practice.

Day four consists of software applications. The Conpass core operation is 90 percent software driven. There are very few mechanical components to the Conpass. This course will explain all of the software functions, capabilities, and limitations.

It will also focus on both organic and inorganic materials recognition. This includes the obvious weapons that are attempted to be smuggled outside of the human body on a regular basis. However, it also shows the materials and methods that a terrorist would use to smuggle items internally. Some examples would be drugs, bio-terrorist weapons in a glass vile that have been inserted into cavities, detonators, plastic explosives, and whatever that we haven't crossed at this point.

Day five then continues with hands-on applications of the system as will as a closing of the training with a certification exam. If the operator does not pass the exam with at least an 80 percent success rate, then he or she must retake

the course. Due to the nature of the output of the device, no operator will be allowed to be certified if they fail the certification test twice.

Every year it is expected that a software driven device will have at least one update or upgrade. Because of this fact, we recommend annual re-certification on the Conpass unit. This certification will consist of a two day course. Day one will cover general use and advanced features of the Conpass device as well as an overview of the product updates and upgrades that are to be installed. Day two will continue the hands on training for the updates and upgrades and end in a re-certification exam. The same policy of 80 percent pass is required as well as not failing more than two re-certification exams.

Moving into hardware safety measures. In order to prevent over exposure of an individual being scanned by the Conpass, certain hardware radiation control measures have already been implemented in the system: (1) radiation warning labelling on the actual unit, (2) a six foot "no walk zone" around the system to keep everyone except the individual being scanned from being exposed to radiation, (3) a light to notify when

the system is energized, (4) emergency stop switches on the scanning platform, if the passenger needs to stop it for whatever reason, operator control desk and at that supervisor area which can be remote, (5) a built in radiation dosimeter to check and balance the radiation output of the system, and (6) a "dead man's" switch on the X-ray tube which automatically closes the shutter for the tube when the software kills the power to the scanning platform.

The software safety measures. As stated before the Conpass is 90 percent software driven. As such, we have implemented the following control measures into the system: (1) a kV and mA lockout. The system will not scan at any other kV or mA other than that which is pre-programmed at the factory. After testing and extensive results, we've seen that we can use 160 kV and 2.5 mA on every individual no matter what their size is without having to fluctuate. So because of that, we have locked the system out where it will only scan at that rate.

Number (2) is an internal dosimeter monitor, which gives warnings and shuts down the scanning of the system if the radiation changes

above pre-set limits. Number (3) is the ability to implement a database which logs all persons scanned and track total exposures. This can be done through bar codes. This can be hooked into any database that the Government may want to use, the jail may want to use or any other location. That runs into privacy issues. Whether or not that will be finally implemented is not our decision, but the capability is there.

Number (4) is a NEAL recording device which videos the entire scanning process of all persons automatically, and then can be reviewed by a supervisor for the possibility of repeated scans by an operator which is trying to deliberately over expose an individual. Number (5) is control of the "dead man's" switch by the software. The system will not release radiation without movement of the platform. If something is not ready or out of calibration, the software will not open the shutter on the tube.

Number (6) is the system automatically records the radiation output of every scan and generates a log for this as well as putting that output with each image. It's on the image in the header. All those logs are to be filed for review

by the FDA at any time. Number (7) is in addition, all service events, calibrations and complaints are to be kept on file for FDA audits at any time, just as the 510(k) for medical devices are required to do.

In conclusion, we welcome the interaction and opportunity to assist the FDA in establishing effective radiation control measures for all ionizing radiation security devices. If more information is required, we are available now or later for further discovery of our product and procedures by the FDA.

I have enclosed this entire prepared statement in the information packets in front of you. There's also a CD with sample images and a brochure. There's the copy of the testing reports done by ITS as far as process validation. Our radiation reports are completed. They are going through their final review at this time. They should be available in about a week and a half of which I will forward those to Mr. Kassady and he can forward them to you. Any questions?

DR. BENSON: You mentioned that the system is locked in 160 kV and 2.5 mA.

MR. CARTER: That's correct.

DR. BENSON: And that's for all persons.

MR. CARTER: Yes.

DR. BENSON: Large, small, in between.

MR. CARTER: That's correct.

DR. BENSON: Okay. And the dose calculation that you have is for an average size person or for your top size person.

MR. CARTER: As far as the point --

DR. BENSON: The effective dose.

MR. CARTER: The effective dose at 0.5 millirems was done on an average size individual. In the radiation report because of the nature of the way the system works using a thin collimated beam, we cannot put a conventional R meter in front of that because you have to cover a large area. We can't do that.

Due to that, the radiation physicists built a mannequin or phantom that has movable channels so that you can move the TLDs to register the radiation at different depths. They did it at both the skin and the absorption and the exit doses. But it was based on an average sized individual.

DR. BENSON: Thank you.

MR. CARTER: The radiation is from seven foot down. If you have a shorter person, yes, they're being exposed but they're only being exposed on their body. The scatter is not such where you're going to get a ton of backscatter at their head.

MS. LOSCOCCO: And that was for the new 160 kV and 2.5 mA.

MR. CARTER: That's correct. Outside the U.S. they kept it in a flexible manner. The product has been deployed for over two years now. It's actually approaching it's third year at the Shiphold (PH) Airport in Amsterdam. At that point, they saw that it was getting too confusing to say I have this kV and this mA and there was no difference in image quality.

So we just came down to say this is the bottom threshold. This is as low as we can go and still produce an effective image that will detect glass, that will detect plastic explosives, obviously metal even if you're hiding it in very dense areas under a fold of skin under your arms. That's how we came up with that dose.

DR. NELSON: Any risks to pregnant women and fetuses?

MR. CARTER: You know. Any time you expose anyone to radiation there are risks. What you have to look at (1) is the product is not going to take the place of metal detectors. It's not going to be implemented where you're herding everybody through the product instead of a metal detector. It's going to be used on a selective basis for secondary screening. If you have a pregnant woman that you want him to send through it, yes you can send her through it. It's not going to be an issue because the regulations already state that you can expose a pregnant woman or an unborn fetus to if I remember correctly it's 100 millirems per year.

DR. LIPOTI: (Away from microphone.)

MR. CARTER: Correct. But on the flip side in an airport, you're not going to have a pregnant woman that's going to be travelling usually all the way up until date of delivery. It can happen, but usually they say don't travel past a certain gestational period.

DR. LIPOTI: But the hazard to the fetus is greater in the early stages of the pregnancy.

MR. CARTER: True. That's correct.

MR. WIGGINS: Just a quick side note on that. One of the issues that's been coming up with the Transportation Security Administration is the standards that are being set are based on percentages of what type of passengers and the outlook of profiling and things like that which will take place in aviation settings. So 30 percent is the number that they're throwing out of what ultimately of passengers being run through this thing over a year period. But pregnant women is a big issue in TSA's mind as well. It's not something they're just going to say we're going to run everybody through.

MR. CARTER: Yes.

DR. LAMBETH: I want to make sure you said it was 0.5 millirems.

MR. CARTER: What's in the brochure and before we locked it down to 160 and 2.5, it was 0.5 millirems.

DR. LAMBETH: What's in your brochure here says less than two microSieverts. Right?

MR. CARTER: Right. That's what I'm saying. At the 160 and 2.5 --

DR. LAMBETH: It's 5.

MR. CARTER: No. We have generated

0.22 to 0.33 millirems worth of radiation as the effective dose per scan.

DR. LAMBETH: Do I have my conversion correct? That's roughly the equivalent of an eighth of a chest X-ray.

MR. CARTER: Correct. A chest X-ray runs anywhere from 30 to 100 millirems depending upon the size of the individual. Then you have fluoroscopy studies that go all the way up to in the thousands of millirems. If you look at what was passed out this morning the CTs were in the multiple hundreds. Yes, it is significantly lower than any medical application. It's about the equivalent of about a one hour flight in an airplane.

DR. LAMBETH: But at 5 if I did it right, it's a quarter of a chest X-ray. Right?

MR. CARTER: Right.

DR. LAMBETH: So your upper limit of yearly exposure represented many chest X-rays. Right?

MR. CARTER: Correct. Here's an extreme example. If you were taking somebody that was commuting to work. They lived in one part of a state and they flew to another part every morning

and then back at night. It's an extreme example, but if you scanned them twice a day every day for a year, that's over 700 scans that you would expose them to. At 0.22 millirems which is what we're putting out as an effective dose, that's roughly 219 millirems. That's about two and a half chest X-rays.

DR. LAMBETH: I came up with a much higher number. I came up with something like 50. Did I do it wrong?

MR. CARTER: 365 times 2 times 0.22.

DR. LAMBETH: A quarter of a chest X-ray per exposure. Right?

MR. CARTER: It depends on what you're calling a chest X-ray. If you're calling 30 to 100 --

DR. LAMBETH: I'm calling 20 microSieverts.

MR. CARTER: Okay. But you're talking in microSieverts, I'm talking in millirems.

DR. LAMBETH: All right.

MR. CARTER: If you want to convert it back to microSieverts, it's 2.2 microSieverts is what 0.22 millirems equates to.

DR. LAMBETH: That's fine. I think

we're okay.

MR. CARTER: Yes.

DR. LAMBETH: We're just multiplying by a factor of 100.

MR. CARTER: It's approximately two and a half chest X-rays if you went through it twice a day every day.

DR. LAMBETH: I don't come up with that. I come up with more like 50. I did the number when it was at 5 which was what was in this literature. This literature says less than 2 microSieverts. Right? Yes. But the original handout was 5 microSieverts. So 5 microSieverts is one-quarter of a chest X-ray.

MR. CARTER: Okay.

DR. LAMBETH: So if I went through this thing 100 times, I have 25 chest X-rays. If I do that every day like you said, I'm talking about doing it 250 days a year going to work only going in, not coming out.

MR. CARTER: Right.

DR. LAMBETH: I'm up to 50.

MR. CARTER: At the 20 millirem level you're talking about on a chest X-ray, yes, that's accurate. If you run up the scale for somebody

larger, obviously that number drops down.

DR. LAMBETH: So the issue is what is a chest X-ray.

MR. CARTER: Correct. The issue is exactly what is a chest X-ray. Probably an easier one is something along the fluoro scale as to what a GI series would be. Those are a little bit --

DR. LAMBETH: If I were working in a diamond mine and I was having to do this once or twice a day for my life, I would think that's a pretty heavy dosage.

MR. CARTER: That's true. Again in the airport scenario, they're not running everybody through it all the time. They're averaging 30 percent. In a diamond mine, what they implemented was the ability to do random scans without the operator knowing it. It was an external software that we loaded on that would give a dummy scan if necessary. That was to help reduce it for that very reason. You're going through it everyday. We don't estimate that anybody's going to be going through it twice a day everyday.

DR. LIPOTI: I have a question for Frank Cerra, not for the industry.

DR. MABUCHI: I have a question to you.

Could you explain to me this report here?

MR. CARTER: Sure.

DR. MABUCHI: How was this done?

MR. CARTER: Hold on one second. Which one are you looking at?

DR. MABUCHI: You have seven charts.

MR. CARTER: Right.

DR. MABUCHI: Five and six.

MR. CARTER: On the top it says five of seven, four of seven. Which one are you looking at so that we're on the same one?

DR. MABUCHI: A number of items were checked by one person and scanned 20 times?

MR. CARTER: What they did when they did the process validation was if you notice there's seven different pages of it.

DR. MABUCHI: Right.

MR. CARTER: It was seven different individuals.

DR. MABUCHI: Seven different inspectors.

MR. CARTER: Right. They then took the different products and scanned them through the 20 times. What these different numbers correlate to was the ease of visualization of what was being

looked for.

DR. MABUCHI: A five is the best and one is the lowest.

MR. CARTER: Right.

DR. MABUCHI: There seems to be some variation among inspectors. If you take a gun it's quite --

MR. CARTER: These are all non-radiographic meaning these were not radiologists that were looking at these. These were engineers that ITS hired to actually do this, so they were looking at what they saw on the monitor and that's how they were coming up with the --

DR. BENSON: Were these items simply in a tray or were they embedded --

MR. CARTER: They were actually placed into a box to hold them and then placed behind two five-gallon jugs of water that had a gelatin and salt mixture to represent the same density as a human body. It would be equivalent of placing the items behind your back and then scanning through. We only require one scan. You run through and whatever you have on you or in you is what we're looking for.

DR. MABUCHI: Now my question is some

people rated wooden knife to be difficult to identify but a couple of persons thought it was quite easy to identify. There seems to be some variation.

MR. CARTER: Correct. The people that were hired, that's what they came up with as far as what they could see. A wooden knife is difficult to see because of its density. When you're talking behind quite a large mass that has the same density as an average size individual, certain things are going to be harder to see.

DR. MABUCHI: How do you cope with that? Do you train inspectors?

MR. CARTER: Well, part of the training is to go over the materials that they would encounter in a normal environment and to show them how to identify them. The systems has the ability to do enhancement of images. What we want to do is keep this as quick as possible. The actual scanning time is ten seconds. Your image is up right after that. We don't want somebody spending four minutes looking at an image trying to figure out all that is in that image. We go through what is obvious and the basics of what they would encounter.

This is not the be all end all for security. This has to be used in conjunction with good law enforcement. It's not just automatically pick anybody out of a line and run them through this. There's no rhyme or reason for that. Running a 90 year old individual through this is probably not going to help them in any way, shape or form as far as security goes. This has to be used in conjunction with other effective law enforcement methods.

DR. SANDRIK: Just a further clarification on this study. Were there any conflicting other objects in this thing or was it basically the uniform water bottles and only this object was there?

MR. CARTER: No. Everything was placed into the box. They were having to decipher through all the things that were in there.

DR. SANDRIK: All these different things were there at one time.

MR. CARTER: Correct. Images from these tests will be attached with the radiation report as well. You can look at them. No, it wasn't just one item in a box and say find the one item. It was multiple items of which you would

encounter in actual daily use. Somebody's probably not going to have just one thing on them.

DR. SANDRIK: Right.

MR. CARTER: They're going to have multiple things that you have to decipher through.

DR. SANDRIK: But you're likely to have a skeletal structure that's obscuring a lot of what might be there as well as opposed to your water bottle phantom which is rather uniform.

MR. CARTER: The water like I said had a mixture in it that was equivalent in density to a human body.

DR. SANDRIK: Right. That's not the --

MR. CARTER: It's not the same.

DR. SANDRIK: The confusing things of ribs and attenuating, less-attenuating, lungs versus heart versus ribs and all these other kinds of structures that could obscure.

MR. CARTER: Correct. The system will pick up a single razor blade. It is effective. After proper training of an operator, they will learn to use their eyes similar to what a radiologist does to scan. What's not supposed to be there stands out to them. Further developments are underway to add autoscanning capabilities that

would take a normal clean body that had normal anatomy structures and compare against the image that was scanned to help aid in that process. It is not there yet.

CHAIRMAN ROTHENBERG: Any other questions?

DR. CASWELL: Yes. In terms of the validation study that you're presenting here, did I hear you correct? These were engineers that did this study.

MR. CARTER: Correct.

DR. CASWELL: So these aren't the type of individuals conducting the study that might be operating this unit when it's in place.

MR. CARTER: These, meaning these were engineers hired by the testing facility. They did not necessarily have an engineering background. The testing facility actually used some of their own people that were working there. Some of them were engineers meaning that's what they did for a living. Others just worked at this engineering facility as secretaries and other things.

DR. CASWELL: Okay. Had they been through your training course at all?

MR. CARTER: Actually no, they had not.

This was just a here, take a look at it. They had not been certified by us as far as explaining what to look for. We kind of threw them to the wolves if you will that find what is in here and point it out and tell me what you see and how easy is it to see that.

DR. LAMBETH: I think your question was whether or not these people were educated. Did they have a Bachelor of Science degree when you say the word "engineer?"

MR. CARTER: Some of them did and some of them did not. They were working at an engineering facility, at ITS. Some of them were secretaries. They were high school graduates but they were not Ph.D.s or Masters.

DR. CASWELL: That may account for some of the variation that we see in the results of this study. It might. I don't know.

CHAIRMAN ROTHENBERG: I just wouldn't refer to them as engineers. So you're going to further provide us with copies of the radiation reports and some images.

MR. CARTER: Well, the images are on the CD that's in front of you. There are numerous formats that you can look at those images. They

are already there as well as scans of both male and female to show that there are no privacy issues. The only thing that stands out on a female is the underwire of a bra. That's it. It's very hard to distinguish other than looking at the structure of the bones that they are females. Yes, we will forward those to Mr. Kassaday and he will forward them to you.

MS. FAHY-ELWOOD: I'm just trying to understand this. The ANSI standard that we talked about before, your system doesn't meet the dose limits of that.

MR. CARTER: As far as for backscatter devices, no, it does not. We are higher than that. We kind of fall in between we're higher than a backscatter device but lower than a medical device. We're not in the resolution to be considered a medical device for 510(k).

MS. FAHY-ELWOOD: Okay. Are there any other portions of that standard that you would not comply with? You must be familiar with it.

MR. CARTER: Not that I'm aware of off-hand. It has all the interlocks and all of the requirements. As far as for safety goes, the only one that I'm aware of is the actual radiation

levels.

MS. FAHY-ELWOOD: That standard isn't just for backscatter though or is it. It's just called security screening systems using X-rays.

DR. LIPOTI: That's a question for the Agency, not for him.

CHAIRMAN ROTHENBERG: Is that your question, Jill? You had a question for Mr. Cerra.

DR. LIPOTI: Yes. Go ahead.

MR. CERRA: The standard is not specifically for backscatter. If these units would meet the limits, they would fall under the scope of the standard. However, the issue that just came up about training, the standard was written again with the backscatter units in mind. It's pretty obvious when there's an object sitting on the surface of the skin as opposed to when the object is inside the body, so that the requirements that we have for training are pretty limited.

That is also the reason why we didn't want the operator to have control over contrast kV and mA and scan time and that type of thing. We felt that a limited set of training would be sufficient to detect all the items that would be detectable on the surface of the skin. When you go

inside the body then I would think that we would want to alter the standard to include some imaging capability on the part of the operator. Radiologists go through years of schooling and they still miss tumors. There will always be something that is missed.

You will have to take a rescan if you think that there may be something but you're not sure. Those types of things are all to be considered. It's not an easy thing. It's not black and white. There may be that instance where the technology is useful if used appropriately. Unfortunately, that's a risk/benefit type of thing. FDA does not regulate the decision making of the benefit. It's not a medical device. We can only regulate the product.

If states do it, then the regulations would differ from state to state. If we do come up with a standard, there is a mechanism that Dan can address where a variance can be obtained for certain uses of the product. Even though they do not meet the standard if it's used for those types of instances where there is an actual benefit, FDA will allow those products to be sold to those customers.

DR. LIPOTI: I'm still not getting to the question. The ANSI standard N43.17 which was adopted April 2, 2002, is entitled Radiation Safety for Personnel Security Screening Systems Using X-rays. I understand that Federal Agencies are under some sort of directive if there is a national consensus standard that you are to use that in your regulatory function. So you would naturally use this ANSI standard. If you were to propose a mandatory standard based on that ANSI standard, the Conpass system would be precluded from being sold in the United States. Am I correct?

MR. CERRA: Right. It would not meet the standard. Like I said, there is a mechanism for variances. They would have to go through the process of having a variance approved. It would not be sold.

DR. LIPOTI: And can you elaborate just a bit on the directive, is it an OMB directive or whatever, that requires a Federal Agency to adopt a standard equivalent to a consensus standard?

MR. CERRA: I am not sure that applies for this particular product. Maybe someone else from FDA can address that.

DR. SHOPE: I think the directive would

be to consider carefully the consensus standard to see if it meets the needs for what we perceive is needed in a mandatory standard. If we had a reason to go beyond what's in the consensus standard, I'm sure we could try to make our case and do the benefit/risk analysis and the supporting impact statements and perhaps implement a standard either less severe or more severe than a consensus standard. The idea is we should carefully consider what's in the consensus standard and use it if appropriate.

CHAIRMAN ROTHENBERG: I didn't hear the answer to one previous question which was other than meeting the dose limit, was there any other aspect of the standards that this device would not meet.

MR. CERRA: At first, I though it would not meet the requirement that the kV and mA would be fixed, but from the talk it seems that they might meet that.

CHAIRMAN ROTHENBERG: So then they would fix it.

MR. CERRA: Right. The main problem I see again is the annual limit which is based on a few sources. If a number of facilities, for

example, movie theaters, sports arenas, airports, court rooms, places of employment, any high security area, if they all would start scanning, then the standard does not make much sense anymore because you need to look at the total exposure to any one individual. It would be impossible to track.

The NCRP recommendations in fact do have some wording to that effect. If a facility which delivers a certain amount of dose, they would have to ensure that the total dose from all other sources of man-made radiation does not exceed 100 millirem a year. They also include an alternative method of sticking to the 25 millirem for the one facility which is reasonable when you consider up to four sources. When you have 50 sources, that doesn't make much sense anymore.

CHAIRMAN ROTHENBERG: But it's still the dose. Other than the dose, all the other aspects once they fix the kV and mA --

MR. CERRA: Right. Off-hand it would probably meet the other requirements.

MR. PLEASURE: I'd like to make a follow up question to your question. The summary of main requirements that you set out included

first the dose level effective dose for each and per year, then secondly benefit versus risk and negligible individual dose less than then, then subject informed of the X-ray exposure and associated risks. So the latter two are also not met in that as I understand the use of this, for example, in a diamond mine, you don't even tell the individual whether they're being exposed or not and extensively to protect them.

Then the benefit versus risk and negligible individual dose doesn't apply because as we've discussed this is not negligible on an individual basis. I would add that I'm somewhat troubled by this association of risk to property, that is platinum, diamonds, precious minerals and its use in those circumstances with security of people and terrorist situations. The two are not comperable.

MR. CERRA: I can't address the current practices of the users of the Conpass in other countries.

MR. PLEASURE: Well, the witness has spoken to that.

MR. CERRA: But assuming that they do tell every employee that they are being exposed to

so much radiation, they might meet the standard. The negligible individual --

MR. PLEASURE: Oh, they don't. They say you may be exposed, so the individual can say to himself or herself maybe I've gone through 50 times but I probably only got exposed once because of the randomness of it. They really don't know. They might have drawn a positive four or five times when they thought they didn't draw any. Do you know what I mean?

MR. CERRA: Again, FDA does not have control over the way it's used. If that requirement were written in the standard, we would have no jurisdiction to verify that. First of all, we wouldn't have that requirement in an FDA standard because it's a use requirement.

MR. PLEASURE: As I understand you, you're saying that you apply certain principles in the development of the standard. The risk/benefit analysis is one of the standards or principles that you must apply.

MR. CERRA: Right.

MR. PLEASURE: So for you to say that we have no concern about its actual use and its purposes, I don't follow that.

MR. CERRA: No. I didn't say we have no concern.

MR. PLEASURE: You do have jurisdiction in developing the standard to consider risk and benefit. Do you not?

MR. CERRA: Do you want to address that?

MR. KASSADAY: Yes. We have jurisdiction to consider the risk and benefit, but any mandatory standard that we write can only address the machine performance. That's why we're going to publish --

MR. PLEASURE: Well, let me follow up on that. We've talked about this before today. If the manufacturer is recommending it for use in let's say Tiffany's to check all personnel as they're leaving randomly like a South African diamond mine, then that is within the scope of your purview. Is it not? That it's a recommended use.

MR. KASSADAY: That would be why we would want to set the dose per screening very low so it doesn't become a problem.

MR. PLEASURE: But of course this product is not at that lower level.

MR. KASSADAY: We can't actually tell

Tiffany's that they can't use the product.

MR. PLEASURE: No. You're dealing with the manufacturer. This manufacturer is recommending its use in situations where diamonds and other minerals are being -- And putting out to purchasers that this is an appropriate use. This was within the range of purposes. That gets you back to a risk/benefit analysis. I don't see why this is beyond your purview.

MR. KASSADAY: We simply don't have jurisdiction. We do have interest in that. That's why we're going to write a recommended use safety statement to go along with that.

MR. PLEASURE: You have jurisdiction over instructions that the manufacturer prepares, for example. You can review the instructions to see whether the instructions are consistent with your standard. If the instructions recommend its use every day as a worker goes in and out of a workplace, then that's within your purview. You do that already with sunlamps.

MR. KASSADAY: Oh, okay. Now I understand what you're saying. Yes. That will be probably in at least the first draft of the mandatory standard, to describe what we would

expect to see in their user instructions. We have written letters back to folks advertising for inappropriate uses before and asked them that they stop. The regulatory authority there is very weak which is why we would want to write the use guideline as well as a standard which would hopefully give some support to states developing regulations to prohibit those sorts of uses.

MR. PLEASURE: Yes. Of course the instructions have impact. If the instructions say it's not appropriate for a particular use, then the state liability standards hook in. The user then is violating the manufacturer's instructions which you have reviewed and created for themselves an intolerable liability situation. You say it's ineffective. I'm not so sure it's so ineffective if you're actually reading these instructions and adopting standards relating to the quality of the instructions. That is a very powerful tool and you do it with sunlamps presumably.

MR. KASSADAY: I see where you're going now. Yes, that's part of the intent of why we're going to publish a guideline on safe use based on the N43 standard which will allow people to do exactly what you're saying. The user instructions

we can prescribe what they must put in there. Once it gets to the use issues and advertising honestly it depends on how it plays out.

DR. SULEIMAN: Let me clarify one thing. The television receiver standard assumed that the product was going to be used a certain amount of viewing time. The sunlamps you're assuming are being used in a certain way. I think the question the dose that the public should receive is established by other regulatory agencies or whatever. I mean we pay attention to that, but I think that shouldn't be driving this issue.

The question in front of the Committee was is this voluntary standard sufficient for some of the new technology. Should there be some changes? Is the dose limit appropriate? For example, let's say it turns out you give 25 millirem per exposure. Then somebody would argue and say you could only use that once a year on an individual. The standards would eventually determine how it's used.

Just like in medicine, you may have limits or guidelines per examination but there's nothing to prevent it from being used over and over again. I think we've discussed this previously.

This really falls into a very grey area. This is not medical use. This is not occupational use. You do now have a benefit associated with technology. So maybe the answer isn't evident right now.

I think we need to know should FDA consider a mandatory standard for this thing. Should the voluntary consensus standard that's been developed be adopted lock, stock and barrel or do we now have a situation here where that's not the case? I think the Committee ought to address that rather than how often it's going to be used.

MR. CERRA: I just would like to clarify one point from the previous question about whether the systems other than the dose limits would comply to the present ANSI standard. I was not considering instructions to the effect that the systems would be used for something other than security. Of course if the manufacturer would make that claim, then the standard is for security screening systems and we do define security in the standard. So it would not meet the standard.

CHAIRMAN ROTHENBERG: Thank you. Yes.

DR. LAMBETH: I think it's important to note that when we use the word "security" we have

certain things in mind. This is a fabulous instrument. It looks like it does fantastic things. On the other hand, if I go to the inner-city schools, there are places where implementing this would be very advantageous. If that were done, these students would be over-exposed in my opinion severely because they might even be going through it more than once a day, more than three times a day. If the standards were not written to specify the usage in certain environments, it would be very deceiving.

MR. CERRA: That's exactly where we are limited because FDA only has certain jurisdiction as to the usage. We can regulate the manufacturer but not so much the user.

DR. LIPOTI: Larry, I was on TEPRSSC in 1998 when TEPRSSC recommended a mandatory standard. I feel that if the mandatory standard were here now that we wouldn't even be hearing about this Conpass system or other systems like it. So I feel very strongly that FDA should move forward with their proposed response as outlined in your presentation to develop mandatory performance standards to base them on ANSI N43.17 and to include in those use covered in a radiation safety

recommendation. I'll make that in the form of a motion if you'd like.

CHAIRMAN ROTHENBERG: Is there a second?

DR. LAMBETH: I second it.

CHAIRMAN ROTHENBERG: Okay. Some discussion. This unit is being brought to our attention due to events related to 9/11 and similar terrorist activities. It does provide the capability that the previously considered systems don't. The question then is where does this fit.

We've heard informal discussion yesterday that for instance the Customs Agency has a capability to take a suspicious person even to a medical facility and subject them to medical level X-rays in order to do whatever investigation they want. This would certainly be a lower dose than that situation. So I think we have to be careful about how we're dealing with the system and be aware that there may not be an alternative system that can provide this level of information at this low-level of dose even though it's a much higher level of dose than the other system. Yes.

DR. LIPOTI: I think that as part of any rule making that it would be encumbant upon the

Agency to investigate alternatives. As part of that investigation they would certainly look into situations where a different system might be useful. In that case a different standard or variance to the particular standard could be granted. But for the overall general standard, I believe that the ANSI N43 Committee did a very good job and put together the standards that TEPRSSC was looking for at the time.

CHAIRMAN ROTHENBERG: But as also Mr. Cerra said this type of unit did not exist at that time. So your motion is they go ahead with the standards. Where does this consideration of this unit fit in?

DR. LIPOTI: Consideration of the other unit would be as either a variance to the particular standard that they put in if it is proved that it will have some benefit in certain instances. In that case, you can very carefully frame the use that it would be allowed for. That it not be in general service for security screening so that we would preclude things like P.S. 105 and New York City installing it at their gates or banks or public buildings or court houses and so forth.

CHAIRMAN ROTHENBERG: Any other

comments?

MR. PLEASURE: Other than I agree with that. Dr. Lipoti described opportunities potentially for variance. That might be discussed. This has been years in the making. I've been here for years too. I remember earlier discussions. While we have needs growing out of 9/11, there are alternatives. We also have a recognized hazard here and a way of dealing with that recognized hazard in a reasonable period of time. If we continue to put this off, I'm concerned that we're doing a disservice to the purposes of the Committee. I think it is time.

DR. SULEIMAN: I want to add one thing. The concerns of the Committee several years ago was not that the doses were very low, not that there wasn't a benefit, but there was concern that over time this technology's doses would start getting higher and it was safer to put a lid on it while we could. So that's why your job is so much more challenging today.

MR. WIGGINS: Am I allowed to add to that?

CHAIRMAN ROTHENBERG: Sure. Why don't you make a statement.

MR. WIGGINS: I think one of the things that's being misconceived here is its use. While on the brochure it states that it looks for bags and things like that which is a European based model, we as a company really don't feel that it's going to be used in arenas and things like that. We're specifically looking for it to be used in security instances such as prisons and the Transportation Security Administration. So I agree that standards need to be set for the product in that arena to keep it away from diamond dealers scanning their employees. I think that's probably the wrong idea. I do believe that the standards need to be set for the security arena.

CHAIRMAN ROTHENBERG: Okay. Well, we have a resolution on the floor, and we've had some discussion. I think unless someone else on the Committee has a comment we're ready to vote at this time. So, all in favor --

DR. LAMBETH: Would you repeat?

CHAIRMAN ROTHENBERG: Which was to go ahead with establishing a standard consistent with the current ANSI recommendations which would also allow for in the consideration of adoption of the standard the Agency should consider whether there

might be a need for variances. Is that right?

DR. LIPOTI: Yes. I think I can say it's on the handout FDA's proposed response that they move forward with a mandatory performance standard based on ANSI N43.17 that also deals with use as covered in a radiation safety recommendation, that they include a discussion of alternatives and that they consider the requirements for variants to their standard.

CHAIRMAN ROTHENBERG: Okay. Are we ready to vote? All in favor?

(Chorus of ayes.)

CHAIRMAN ROTHENBERG: Opposed?

(No response.)

CHAIRMAN ROTHENBERG: Abstains? Okay. We had one abstention. I think we had ten for. Any other abstentions or opposed?

(No response.)

CHAIRMAN ROTHENBERG: I guess we had ten in favor and one abstention. Thank you for your presentation, all of you. We're now ready to move on to the next item. We're basically finished with the substantive discussions of various issues which were on the agenda. Does anybody on the Committee have any additional items? We're going

to talk about date for a future meeting. But in terms of items for discussion. Yes.

DR. NELSON: I wanted to follow up my question. I don't know if Dr. Cyr is here anymore. I wanted to follow up on my question this morning about what types of outcomes are being evaluated in the cellular phone radiation studies. It's not necessary that the question be answered right now. I'd like to at least propose that at our next meeting perhaps -- Oh, you are here.

DR. CYR: I missed the first part of your question.

DR. NELSON: Okay. Well, earlier this morning --

CHAIRMAN ROTHENBERG: With Ms. Gill.

DR. NELSON: Right. Ms. Gill reported on the safety inquiries into cellular phones. I had asked her what sorts of outcomes were being evaluated. She didn't know.

DR. CYR: We have an agreement with industry, a CREDA, in which we are monitoring several kinds of studies. Right now there are three different levels of that. The first part is out and the studies are beginning. They are studies on micronuclei. There were cell culture

studies in which they found changes in terms of micronuclei. We wanted to repeat those studies in various laboratories paying particular emphasis on the dosimetry and making sure that there were no hot spots, no possible thermal effects and doing it on a large scale. There are three labs all set up and ready to go to do micronuclei studies.

The second part will be to look at the dosimetry that was reported, epidemiology effects, namely brain tumors and things like that. The requirements have been written but there has been no call for proposals. That's the next step. We hope to get along with that. In a year or so, we're supposed to convene a panel of experts and figure out whether there are other studies that need to be done in addition to the micronuclei studies and the exposure assessment studies.

As you know, I've done sunlamps and just recently I've taken over cell phones because our leading expert didn't retire but he moved on to another job at EPA. They asked me to take this on temporarily. We are in the process of trying to find a full-time replacement person who will take over the issue on cell phones.

DR. NELSON: Thank you.

CHAIRMAN ROTHENBERG: Okay. Anything else? Okay. Then Dr. Suleiman wanted to try to find some dates at least maybe a couple of dates or approximate time to consider for our next meeting.

DR. SULEIMAN: All right. Let me propose February 6th which is a Thursday. Let's put 5th and 6th. The other one I would propose at this point would be I guess March 5th and 6th. I don't see any conflicts on our calendar at this point in time. You can check back. We can communicate with E-mail unless somebody knows right now that there is a conflict with any of those.

CHAIRMAN ROTHENBERG: Those are what days of the week?

DR. SULEIMAN: Those are both Wednesday and Thursday.

CHAIRMAN ROTHENBERG: I think it was Dr. Lambeth who said Thursday is better than Wednesday.

DR. LAMBETH: That's okay.

DR. BENSON: Could I be the naive new person and make a proposal that we perhaps meet more often or perhaps have some kind of consensus thing going on by E-mail? For instance, the revised wording of the warning label from the

sunlamp people, does that have to wait until next February or could we circulate it by E-mail and consider it and discuss it? Just move the time table up for some of those things that we've already talked about and just need a little buffing up.

CHAIRMAN ROTHENBERG: I think first of all with regard to having more frequent meetings, we do have some budget limitations, at least we have had in the past.

DR. BENSON: Okay.

CHAIRMAN ROTHENBERG: With regard to E-mail --

DR. BENSON: E-mail is still free as far as I know.

DR. SULEIMAN: What I would propose is that literally we don't have to run the wording by you. If we had to formally, then we'd have to convene the meeting and go through a lot of logistical problems. However, I don't see anything wrong with sending draft proposals of the wording to all the Committee members and getting their comments. You'll have the same effect, same impact and we don't have to go through the formalities. I'll promise you that. I know Howard would be more

than willing to do that. That way you can keep informed on some of the developing issues.

DR. BENSON: Okay.

CHAIRMAN ROTHENBERG: Okay. Well, I think there are no further issues at this point. Oh, sorry. Dr. Shope.

DR. SHOPE: Just one comment. I was passing around a copy of the web site for the CT whole-body screening issue. I just want to mention if anybody hadn't seen that and wanted to, it's somewhere on the table there.

CHAIRMAN ROTHENBERG: It was a color printout.

DR. SHOPE: Yes, a color printout.

CHAIRMAN ROTHENBERG: Here it is. So anybody who would like to see it, we'll pass it around. It is available.

DR. SULEIMAN: Let me mention something Dr. Caswell just reminded me of. He said that you had sent us a copy. I had sent a copy with a link to the Committee members. I forgot about that. It should be in your E-mails. We can resend it out again.

CHAIRMAN ROTHENBERG: Okay. Since there are no further items. Oh, there is one

further item.

DR. SULEIMAN: I think we're losing five of you, but I don't remember which five. Alice, you're on another year. Right?

MS. FAHY-ELWOOD: I think so.

DR. SULEIMAN: Who's the Government person we're losing?

MS. FAHY-ELWOOD: I think Greg Lotz.

DR. SULEIMAN: That's right and he left at noon. Who is it?

MS. FAHY-ELWOOD: Yes, I think Q. Balzano.

DR. SULEIMAN: That's right. Quirino Balzano from Motorola.

MR. KACZMARCK: And John Sandrik.

DR. SULEIMAN: John, thanks an awful lot. We're not sure I think you may be on --

MR. PLEASURE: One more year?

DR. SULEIMAN: Yes. But you may want to resign. We were talking about that.

MR. PLEASURE: We've talked about that.

CHAIRMAN ROTHENBERG: Not because we don't want you.

MR. PLEASURE: Right.

CHAIRMAN ROTHENBERG: We haven't asked

you to go.

DR. SULEIMAN: Usually, I would have the names in front of me. To make it faster, I figured I would ad lib it this way. Clearly those of you who are going off, we appreciate what you have done. Those of you who aren't rotating off, we're still appreciative of what you're doing.

CHAIRMAN ROTHENBERG: Let me also thank all of you for taking time out of your busy schedules to participate in this. Those of you that are going off, it's been a pleasure for me to have served with you. We really appreciate your effort. Okay. I guess the meeting is adjourned. Thanks everyone. Off the record.

(Whereupon, the above-entitled matter concluded at 3:48 p.m.)

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